

EXHIBIT 7



Washington, D.C. 20201

MAY 30 2006

TO: The Secretary
Through: DS _____
COS _____
ES _____

FROM: Inspector General

SUBJECT: Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005 (A-06-06-00063)

PURPOSE

As required by section 6001 of the Deficit Reduction Act (DRA) of 2005, which amended section 1927 of the Social Security Act (the Act), we are providing you with our report on determining average manufacturer prices (AMPs). Our specific mandate was to (1) review the requirements for, and manner in which, AMPs are determined under section 1927 of the Act and (2) recommend appropriate changes by June 1, 2006.

INFORMATION TEXT

To summarize our report, existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. Our previous and ongoing work has found that the manufacturers reviewed interpret AMP requirements differently. Specifically, our findings demonstrate the need to clarify the definition of retail class of trade and the treatment of pharmacy benefit manager rebates and Medicaid sales in AMP calculations. Consistent with our findings, industry groups also emphasized the need to clarify certain AMP requirements. Further, they raised additional issues related to the implementation of DRA provisions.

Because the DRA expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors.

Our report includes several recommendations for use in promulgating regulations and guidance to clarify AMP requirements.

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If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104.

A handwritten signature in cursive script, reading "Daniel R. Levinson".

Daniel R. Levinson

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**DETERMINING AVERAGE
MANUFACTURER PRICES FOR
PRESCRIPTION DRUGS UNDER
THE DEFICIT REDUCTION
ACT OF 2005**



Daniel R. Levinson
Inspector General

May 2006
A-06-06-00063

Office of Inspector General

<http://oig.hhs.gov>

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EXECUTIVE SUMMARY

BACKGROUND

Medicaid Drug Rebate Program

Section 1927 of the Social Security Act (the Act) established the Medicaid drug rebate program. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Section 1927(b)(3) of the Act requires a participating manufacturer to report quarterly to CMS the average manufacturer price (AMP) for each covered outpatient drug. Section 1927(k)(1) defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

CMS uses AMP to calculate a unit rebate amount for each covered outpatient drug and provides the unit rebate amounts to the States. The States determine the total rebates that participating manufacturers owe by multiplying the unit rebate amount by the number of units of the drug dispensed to Medicaid beneficiaries.

Deficit Reduction Act of 2005

The Deficit Reduction Act (DRA) of 2005 requires the Secretary of the Department of Health and Human Services to provide AMP data to the States on a monthly basis beginning July 1, 2006. These data will provide States with pricing information that was generally not available previously, and States may choose to use AMP in setting reimbursement amounts. In addition, the DRA establishes AMP as the new reimbursement basis for drugs subject to Federal upper limit requirements.

The DRA requires the Office of Inspector General (OIG) to (1) review the requirements for, and manner in which, AMPs are determined under section 1927 of the Act and (2) recommend appropriate changes by June 1, 2006. Pursuant to the DRA, CMS must promulgate, by July 1, 2007, a regulation that clarifies those requirements after considering OIG's recommendations.

OBJECTIVE

Our objective was to review the requirements for, and manner in which, manufacturers determine AMPs under section 1927 of the Act.

SUMMARY OF RESULTS

Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. OIG's previous and ongoing work, which has primarily focused on how manufacturers calculate AMP, has found that the manufacturers reviewed interpret AMP requirements differently. Specifically, our findings demonstrate the need to clarify the definition of retail class of trade and the treatment of

pharmacy benefit manager rebates and Medicaid sales in AMP calculations. In addition, work related to the use of AMP by CMS and other agencies highlights the need to consider the timeliness and accuracy of manufacturer-reported AMPs. Consistent with our findings, industry groups also emphasized the need to clarify certain AMP requirements. Further, they raised additional issues related to the implementation of DRA provisions.

Because the DRA expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors.

RECOMMENDATIONS

We recommend that the Secretary direct CMS, in promulgating the AMP regulation, to:

- clarify requirements in regard to the definition of retail class of trade and the treatment of pharmacy benefit manager rebates and Medicaid sales and
- consider addressing issues raised by industry groups, such as:
 - administrative and service fees,
 - lagged price concessions and returned goods,
 - the frequency of AMP reporting,
 - AMP restatements, and
 - baseline AMP.

We also recommend that the Secretary direct CMS to:

- issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and
- encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In commenting on a draft of this report, CMS stated that it would address each of the recommended areas, as well as the areas raised by industry groups, in its proposed regulation. CMS also stated that it would evaluate the need for additional guidance. CMS's comments are included as Appendix G.

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INTRODUCTION

BACKGROUND

Medicaid Drug Rebate Program

Section 1927 of the Social Security Act (the Act) established the Medicaid drug rebate program. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. Section 1927(b)(3) of the Act requires a participating manufacturer to report quarterly to CMS the average manufacturer price (AMP) for each covered outpatient drug. Section 1927(k)(1) defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

CMS uses AMP and, in some cases, best price data to calculate a per unit (e.g., per pill) rebate amount for each covered outpatient drug and provides the unit rebate amounts to the States.¹ The States determine the total rebates that participating manufacturers owe by multiplying the unit rebate amount for a specific drug by the number of units dispensed to Medicaid beneficiaries.

Deficit Reduction Act of 2005

The Deficit Reduction Act (DRA) of 2005 contains several provisions affecting the Medicaid drug rebate program and Medicaid drug reimbursement. Sections 6001(c) and (g) of the DRA require the calculation of AMP without regard to customary prompt pay discounts effective January 1, 2007. Section 6001(b) requires the Secretary of the Department of Health and Human Services to provide AMP data to the States on a monthly basis beginning July 1, 2006. These data will provide States with pricing information that was generally not available previously, and States may choose to use AMP in setting reimbursement amounts. In addition, the DRA establishes AMP as the new reimbursement basis for drugs subject to Federal upper limit requirements. Section 6001(a) of the DRA requires that, effective January 1, 2007, Federal upper limits will be based on 250 percent of AMP for the drug with the lowest AMP rather than 150 percent of the lowest published price for therapeutically equivalent products.

Section 6001(c)(3)(A) of the DRA requires the Office of Inspector General (OIG) to (1) review the requirements for, and manner in which, AMPs are determined under section 1927 of the Act and (2) recommend appropriate changes by June 1, 2006. Section 6001(c)(3)(B) requires that CMS promulgate, by July 1, 2007, a regulation that clarifies those requirements after considering OIG's recommendations.

¹Section 1927(c)(1)(C) defines best price as the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity, excluding certain sales.

Centers for Medicare & Medicaid Services Guidance

Since the Medicaid drug rebate program began in 1991, CMS has issued a regulation (42 CFR § 447.534) addressing only manufacturers' record retention requirements and time limits for submitting AMP recalculations. CMS has also issued guidance to manufacturers in the form of a standardized drug rebate agreement with manufacturers and memorandums called Medicaid drug program releases (releases).

The rebate agreement further defines AMP and provides a definition of wholesalers:

- AMP is defined as “the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number).” The rebate agreement further specifies that cash discounts and all other price reductions that reduce the actual price paid are included in AMP (section I(a) of the rebate agreement).
- A wholesaler is defined as “any entity (including a pharmacy or chain of pharmacies) to which the labeler [manufacturer] sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug” (section I(ee) of the rebate agreement).

Section I(a) of the rebate agreement also provides that the AMP “for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.” Manufacturers can have payment arrangements with entities that do not take title to or possession of drugs. These arrangements can affect the price realized by the manufacturer without changing the price paid by the purchaser that takes title to or possession of the drugs.

To provide additional clarification on rebate issues, CMS sent 72 releases to drug manufacturers from 1991 through March 2006. These releases typically focused on specific definitional or calculation-related concerns.

Medicaid Reimbursement of Covered Outpatient Drugs

Each State is required to submit a Medicaid State plan to CMS describing its payment methodology for covered drugs. Federal regulations (42 CFR § 447.331(b)) require, with certain exceptions, that a State's reimbursement for drugs not exceed, in the aggregate, the lower of the estimated acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge to the public for the drugs. CMS allows States flexibility in defining estimated acquisition cost.

For certain drugs, States also use the Federal upper limit to determine reimbursement amounts. CMS has established Federal upper limit amounts for more than 400 drugs that meet specified criteria. Pursuant to 42 CFR § 447.332(b), Federal upper limit amounts are currently based on 150 percent of the lowest published price for therapeutically equivalent products.

States have generally based estimated acquisition cost on readily available published prices, typically the average wholesale price (AWP). OIG has found that Medicaid drug reimbursement based on AWP often exceeds pharmacies' actual acquisition costs and the prices paid by other Federal programs. AWP data have several critical flaws. AWP is not defined in statute or regulation, is not necessarily linked to actual sales transactions, and is not easily verifiable. While certain aspects of AMP need to be addressed, AMP has several advantages over AWP as a basis of reimbursement. In contrast to AWP, AMP is statutorily defined, is calculated from actual sales transactions, and is subject to audit.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to review the requirements for, and manner in which, manufacturers determine AMPs under section 1927 of the Act.

Scope

We limited our review to information obtained through OIG work since 1991 and discussions with representatives of stakeholders in the Medicaid drug rebate program (manufacturers, pharmacies, distributors, and States). The audit objective did not require that we identify or review any internal control systems.

We performed our fieldwork during March and April 2006.

Methodology

To accomplish our objective, we:

- reviewed the appropriate sections of the DRA, section 1927 of the Act, the rebate agreements between CMS and drug manufacturers, and applicable CMS releases;
- met with congressional staff to discuss the OIG requirements in the DRA;
- interviewed CMS officials;
- analyzed and compiled past and ongoing OIG work related to drug manufacturers, AMP calculations, and the use of AMP;²
- met with three manufacturer groups, three pharmacy groups, one distributor group, and one State government group to discuss their concerns related to AMP calculations and the DRA; and
- analyzed written comments provided by six of these groups.

²Many of the OIG reports contain proprietary information and are therefore not available to the public.

We conducted our review in accordance with generally accepted government auditing standards.

RESULTS OF REVIEW

Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. OIG's previous and ongoing work has demonstrated that the manufacturers reviewed interpret AMP requirements differently. Consistent with our findings, industry groups also emphasized the need to clarify requirements. Further, they raised additional issues related to the implementation of DRA provisions. Because the DRA expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors.

SUMMARY OF OFFICE OF INSPECTOR GENERAL WORK

Our work on Medicaid drug rebates has focused on how manufacturers calculate AMP and how CMS and other agencies use AMP. Findings in these areas demonstrate the need to clarify the definition of retail class of trade and the treatment of pharmacy benefit manager (PBM) rebates and Medicaid sales in AMP calculations. One issue fundamental to the proper treatment of PBM and other rebates is whether AMP should represent the net price realized by manufacturers or the price paid by purchasers that take possession of the drugs. Our findings also highlight the need to consider the implications of previously reported problems in the timeliness and accuracy of manufacturer-reported AMPs.

Calculating Average Manufacturer Price

Our first review, initiated in 1991, found that four drug manufacturers used three different methods to calculate AMP; they based the calculations on gross sales to wholesalers, net sales to wholesalers, or direct retail sales and retail sales reported by wholesalers. We recommended that CMS survey other manufacturers to identify the methods used to determine AMP and develop a more specific policy for calculating AMP that would protect the Government's interest and be equitable to manufacturers.

At CMS's request in the mid-1990s, we reviewed the AMP submissions of two manufacturers that had revised their AMP calculation methodologies. For the first manufacturer, we were unable to express an opinion on the revised methodology because the manufacturer lacked adequate documentation to support its changes. The second manufacturer's methodology revision primarily involved the inclusion of price concessions to customers that the manufacturer considered to be retail. For example, the manufacturer decided that price concessions to mail-order pharmacies, nursing home pharmacies, PBMs, independent practice associations, and clinics represented the retail class of trade. Based on our limited review, we disagreed with the manufacturer's designation of these customers as part of the retail class of trade; therefore, we believed that the price concessions should not have been included in AMP. However, at the time, no guidance addressed the retail class of trade issues that we reviewed. Subsequent to that review, CMS issued release 29, which provided guidance on the treatment of some of these customers.

In 2003, we initiated reviews of four manufacturers. We selected these manufacturers because they had reported to CMS that they had changed their AMP calculation methodologies and had, as a result, received State refunds of previously paid rebates. We once again found differences in the ways that manufacturers treated certain elements of their AMP calculations. As discussed below, these reviews identified significant issues related to the treatment of PBM rebates and Medicaid sales.

Treatment of Pharmacy Benefit Manager Rebates

A major factor contributing to inconsistencies in manufacturers' AMP calculations is the business relationship between a manufacturer and various groups involved in distributing drugs. PBMs, in particular, have assumed a prominent role in the drug distribution network.

Health plans and third-party payers often hire PBMs to help manage the drug benefits paid by those plans. PBMs may act on behalf of many types of customers, of which some could be considered a part of the retail class of trade. Unless a PBM has a mail-order component, it generally does not purchase drugs or take delivery of or title to the drugs.

PBMs may negotiate and receive rebates and other payments from manufacturers based on services provided (e.g., formulary development and communications to patients) and/or based on a drug's utilization or market share. PBMs may share or "pass through" to their customers some or none of the rebates or fees they receive from manufacturers. Manufacturers are generally not parties to the contracts between PBMs and their customers. Manufacturers have indicated that they may not know how much, if any, of the rebates received by a PBM are passed on to the PBM's customers. Retail pharmacy groups have indicated that PBM rebates do not get passed on to pharmacies.

Three of the four manufacturers audited as part of our ongoing work reduced their AMP values for rebates paid to PBMs. The inclusion of PBM rebates in an AMP calculation reduces AMP, resulting in lower Medicaid rebates to the States.

- Two manufacturers included all rebates paid to PBMs when calculating AMPs. One manufacturer believed that PBMs act like wholesalers because they manage the flow of drug products through their network of pharmacies. The other manufacturer indicated that, with the lack of formal guidance addressing how to handle PBM rebates, nothing precluded it from including payments to PBMs.
- The third manufacturer included a portion of its PBM rebates in the calculation of AMP based on an analysis of the health plans represented by PBMs. The manufacturer determined the percentage of health plans that it considered to be "retail," allocated rebates paid to PBMs for those plans, and included that percentage of the rebates in the AMP calculations.

Conversely, the fourth manufacturer did not include rebates paid to PBMs in its AMP calculations. This manufacturer decided not to characterize transactions with PBMs as "sales"

because PBMs do not take possession of drugs; therefore, this manufacturer believed that including the rebates in AMP would not be consistent with section 1927 of the Act.

Neither section 1927 of the Act nor the rebate agreement addresses the issue of how to treat rebates that manufacturers pay to PBMs. CMS issued three releases in 1997 that discussed PBMs. Releases 28 and 29 stated that “drug prices to PBMs” had no effect on AMP calculations unless the PBM acted as a wholesaler as defined in the rebate agreement. (CMS did not explain what it meant to act as a wholesaler in the context of PBMs, which do not typically take delivery of and title to drugs.) In release 30, CMS recognized existing confusion relating to the treatment of PBMs and stated that it intended to reexamine the PBM issue and hopefully clarify its position in the future. However, to date, CMS has not done so.

Treatment of Medicaid Sales

Another factor contributing to inconsistencies in manufacturers’ AMP calculations is the different interpretation of what sales should be included/excluded in the calculations. For example, our recent reviews found that some manufacturers excluded from the calculations a portion of sales to pharmacies that dispense prescription drugs to Medicaid beneficiaries. Two manufacturers subtracted Medicaid sales from their AMP calculations. Removing Medicaid sales from gross sales generally lowered AMP for these manufacturers.

Medicaid does not directly purchase drugs from manufacturers or wholesalers but reimburses pharmacies after the drugs have been dispensed to Medicaid beneficiaries. Because a pharmacy that dispenses drugs to Medicaid beneficiaries likely dispenses drugs to non-Medicaid patients from the same containers of the product, it would be nearly impossible for a manufacturer to specifically identify a sale that would be considered a Medicaid sale. However, two manufacturers estimated Medicaid sales amounts to subtract from the AMP calculations by multiplying the number of units that States reported when billing the manufacturer for rebates by the price the wholesaler paid for the drug.

The two manufacturers justified removing Medicaid sales for different reasons. One manufacturer indicated that because the rebate agreement did not allow a reduction of gross sales by the value of Medicaid rebates paid in calculating AMP, the sales associated with the rebates should also be excluded. The other manufacturer likened Medicaid sales to State Pharmaceutical Assistance Programs, which provide drug coverage to certain qualified individuals. CMS’s release 29 provides that sales under these programs should not be considered in AMP, so the manufacturer concluded that Medicaid sales should also not be considered.

Like Medicaid, State Pharmaceutical Assistance Programs do not purchase drugs from manufacturers or wholesalers but reimburse pharmacies for dispensing the drugs and may receive rebates from manufacturers. However, release 29 did not address the question of whether only the rebates paid to the programs should be excluded from AMP calculations (similar to the statutory requirement to exclude Medicaid rebates) or whether the underlying sales associated with the rebates should also be excluded.

We disagree with the reasoning of both manufacturers. The exclusion of Medicaid sales is not addressed in section 1927 of the Act, the rebate agreement, or any of the releases. In addition, retail pharmacies that very often dispense drugs to the Medicaid population would seem to fall squarely within the plain language of the “retail pharmacy class of trade” provision of the AMP definition.

Using Average Manufacturer Price in Reimbursement Calculations

Concerns related to AMP calculations take on additional significance given that the DRA has expanded the use of AMP. Prior to the DRA, AMP was primarily used as the fundamental component in determining the amount of Medicaid drug rebates. However, the DRA provides for the use of AMP as a basis for Medicaid reimbursement for the first time. Issues arising from the use of AMP in connection with the 340B drug-pricing program provide useful lessons as CMS (and potentially the States) prepares to use AMP as a basis for Medicaid reimbursement.

The 340B program, established by the Veteran’s Health Care Act of 1992, is a drug discount program for certain qualified covered entities (including Public Health Service and other safety-net providers) that serve vulnerable patient populations. Under the 340B program, manufacturers agree to charge participating covered entities prices that are at or below a specified maximum price (known as the ceiling price) for purchases of outpatient drugs (42 U.S.C. § 256b(a)(1)). The ceiling prices are based, in part, on the reported AMP and unit rebate amounts for covered drugs (42 U.S.C. § 256b(a)).

In our review of the 340B program, we found two primary issues that have implications for the use of AMP as the basis of Medicaid reimbursement: the timely submission of AMP data by manufacturers and the accuracy of reported AMP data.

Our review found that manufacturers did not always report AMP in a timely manner or, in some cases, did not report AMP at all.³ For example, the 340B ceiling price file for the first quarter of 2005 was missing 28 percent of the prices necessary to calculate 340B ceiling prices. For 70 percent of these missing prices, the file did not contain the AMP.

Manufacturers are required to report their drugs’ AMPs and, where applicable, the best price within 30 days after a quarter’s end so that CMS can calculate the drug’s Medicaid unit rebate amount (section 1927(b) of the Act). CMS staff reported that if the data were late, they typically contacted the manufacturers that submitted incomplete data and requested prompt submission. According to CMS, most manufacturers were responsive to these contacts and typically provided the missing data with their next quarter’s submission.

While timely submission of AMP data is important to the Medicaid rebate program, it will become even more critical when Medicaid uses AMP data as a basis for reimbursement. Late submissions of AMP data may delay, rather than prevent, State Medicaid agencies’ rebate collections. However, late submissions may prevent CMS from calculating accurate Federal upper limit prices and hinder States’ ability to accurately reimburse pharmacies.

³“Deficiencies in the Oversight of the 340B Drug Pricing Program” (OEI-05-02-00072, October 2005).

Our reviews have also found issues related to the accuracy of reported AMP data. CMS's edit of a manufacturer's AMP submission is designed to reject an AMP that is 50 percent higher or lower than the manufacturer's submission for the previous quarter. When the edit detects aberrant AMP values, CMS sends a report to the manufacturer requesting corrected information. While inaccuracies may ultimately be corrected, inaccurate AMP submissions also affect the timeliness of CMS's receipt of the correct AMPs and could affect reimbursement made before the data are corrected.

In our review of States' accountability and control over Medicaid rebate collections, we noted problems with unit rebate amounts of zero that resulted from inaccurate AMPs and the untimely reporting of AMPs.⁴ This created accountability problems in some States' administration of their rebate programs and could also create problems for reimbursement based on AMP.

SUMMARY OF INDUSTRY GROUP PERSPECTIVES

We met with eight groups that represented a cross-section of interested stakeholders, including manufacturers, pharmacies, distributors, and States, and invited the groups to provide written comments for our consideration. Six of the eight groups provided written comments. We have summarized some of their comments and suggestions below and have included their complete written comments in Appendixes A through F. We believe that the industry comments provide CMS with valuable information to use in clarifying requirements related to calculating AMP, using AMP in reimbursement calculations, and implementing provisions of the DRA.

Calculating Average Manufacturer Price

Definition of Retail Class of Trade

Consistent with our own findings, industry groups emphasized the need for clarification of entities included in the retail class of trade for AMP calculations. The manufacturer groups commented that CMS had not fully addressed which classes of trade are to be considered "retail" for purposes of calculating AMP. Release 29 clarified the retail status of some classes of trade but not all. The manufacturer groups pointed out the lack of guidance for classes of trade such as physicians, clinics, and patients (i.e., coupons or other patient discount programs).

While they agreed on the need for clarification, respondents presented different suggestions for addressing this issue. One manufacturer group suggested that the retail class of trade be defined to include only entities that dispense drugs to the general public on a walk-in basis (e.g., retail, independent, and chain pharmacies) and mail-order pharmacies that dispense drugs to patients who do not receive other specialized or home care services from the entity. Another manufacturer group did not recommend a particular definition but encouraged a definition that stipulates the criteria or rationale used to determine whether classes of trade are retail or nonretail.

The pharmacy groups advocated that the retail class of trade be limited to traditional retail outlets such as chain and independent pharmacies. These groups also believed that manufacturer sales

⁴"Multistate Review of Medicaid Drug Rebate Programs" (A-06-03-00048, July 6, 2005).

to mail-order and nursing home pharmacies should not be considered retail for the purposes of calculating AMPs.

The decision to include or exclude certain entities has important implications for AMP. The entities in question, i.e., physicians, clinics, and mail-order and nursing home pharmacies, may not all purchase drugs at the same price, so including or excluding sales to these entities may have the effect of decreasing or increasing AMP.

Treatment of Pharmacy Benefit Manager Rebates

Also in keeping with our findings, respondents raised issues surrounding the treatment of PBM rebates. One manufacturer group commented that CMS's limited PBM guidance had caused confusion. This group did not want any requirement that obligates manufacturers to gather information from "downstream" entities (e.g., PBM customers). The group indicated that contracts between PBMs and their customers do not have uniform provisions on the sharing of manufacturer rebates, and the group was not sure whether manufacturers could contractually require the information. Additionally, the group noted that it would be difficult to incorporate such information into AMP calculations.

The pharmacy groups and the distributor group all favored excluding PBM rebates from the AMP calculation (i.e., not subtracting rebate payments from the sales dollars) because the rebates are not passed on to the retail pharmacies.

Treatment of Administrative and Service Fees

Industry groups also sought clarification of the treatment of administrative and service fees, and respondents raised some specific points for CMS to consider in determining how to treat these fees. One manufacturer group noted that release 14 was the only guidance addressing fees and that it did not provide needed specificity. Release 14 states that administrative fees should be included in AMP if they are paid to an entity whose sales are included in the AMP calculation and if the fees ultimately affect the price realized by the manufacturer.

Another manufacturer group suggested that if CMS were to apply the average sales price criteria to service and administrative fees, it should clarify whether the definition of bona fide service is satisfied in relation to traditional wholesaler functions (e.g., pick, pack, and ship services).⁵ In addition, one manufacturer group did not want the decision to include or exclude fees to require a manufacturer to obtain information regarding transactions between downstream entities.

⁵The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established the average sales price as the basis for determining reimbursement amounts for most Medicare Part B drugs. CMS guidance (question and answer 3318 on the CMS Web site at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>) indicates that administrative fees are included in the average sales price if they are paid to an entity whose sales are included in the average sales price calculation and if they ultimately affect the price realized by the manufacturer. Additionally, question and answer 4136 indicates that "bona fide service fees that are paid by a manufacturer to an entity, that represent fair market value for a bona fide service, and that are not passed on" to the entity's clients or customers are not included in average sales price calculations because the fees would not ultimately affect the price realized by the manufacturer. Ongoing OIG audits have shown that manufacturers treat average sales price-related administrative and service fees inconsistently.

The pharmacy groups and the distributor group, however, did not believe that these fees should be used to reduce sales values included in AMP calculations.

Including these fees would generally result in lower AMPs and, therefore, lower rebates and reimbursement (for those drugs with reimbursement based on AMP).

Lagged Price Concessions and Returned Goods

The industry groups indicated that the timing of price concessions and returned goods could create inconsistent AMPs from one period to the next, thereby creating problems with using AMP as a basis for reimbursement.

One manufacturer group stated that a methodology should be prescribed to account for late-arriving discount and rebate data. Another manufacturer group did not specifically mention lagged price concessions but commented that AMP should be calculated in such a way that would avoid the need for retroactive adjustments. The group noted that returns should be addressed. Yet another manufacturer group recommended that CMS encourage “smoothing” to accommodate transaction timing.

One pharmacy group and the distributor group recommended that lagged rebates and discounts be smoothed over a rolling 12-month period, similar to the manner in which average sales price is calculated. They also recommended that returned goods not be considered in AMP calculations.

Using Average Manufacturer Price in Reimbursement Calculations

One manufacturer group stated that AMP should not be used to set reimbursement rates until a standardized methodology for calculating AMP has been established. The group noted that the use of AMP in setting the Federal upper limits is scheduled to start January 1, 2007, but CMS is not required to issue its regulation until July 1, 2007. Another manufacturer group commented that the regulations should ensure that AMPs used in reimbursement are calculated in a way that avoids the need for restatements and unnecessary quarter-to-quarter volatility. The group also recommended that OIG caution States about potential volatility in AMP that may occur as a result of this report and CMS’s expected regulation. A third manufacturer group commented that large-volume purchasers such as large national chain drug stores could affect AMP and result in inadequate reimbursement for independent pharmacies.

The pharmacy groups expressed concern about using AMP, which was created for rebate purposes, as a benchmark for reimbursement.

Deficit Reduction Act Implementation Issues

Frequency of Average Manufacturer Price Reporting

The manufacturer groups noted that the DRA required monthly AMP reporting but did not change the quarterly rebate-reporting period in the Act. Because of this discrepancy, the groups indicated that it was unclear whether manufacturers would be required to calculate and report:

- a monthly AMP using 1 month's data;
- a monthly AMP using the most recent 3 months' data (e.g., a rolling average methodology);
- a monthly AMP using a methodology different from that used for rebate purposes;
- a quarterly AMP separate from the monthly AMPs; or
- a quarterly AMP that is an average of the monthly AMPs.

Average Manufacturer Price Restatements

One manufacturer group wanted to know whether AMP calculations would be considered final when submitted or whether manufacturers would be able, or even required, to restate their AMP calculations when they recognize that a prior AMP calculation was incorrect. Another manufacturer group asked whether AMP resubmissions would be permitted. A third manufacturer group believed that manufacturers should be able to restate quarterly AMPs, but not the monthly AMP.

Baseline Average Manufacturer Price

Baseline AMP represents the AMP calculated for the first full quarter a drug is on the open market. It is used to determine whether an additional rebate is owed to the Medicaid program. Essentially, if an AMP rises in value faster than the baseline AMP (after adjusting for inflation) the manufacturer must pay an additional rebate. Pursuant to the DRA, prompt pay discounts should no longer be considered in calculating the current quarter's AMP. Previously, section 1927(k)(1) of the Act required that prompt pay discounts be used to reduce the sales values included in the baseline AMPs. Excluding these discounts could potentially result in an increase in AMPs that exceeds the inflation adjustment, thereby triggering the additional rebate. Two manufacturer groups expressed concern that manufacturers could be penalized if baseline AMPs were not adjusted to conform to the new AMP definition. The groups indicated that manufacturers would pay an unfair amount of additional rebates related to the methodology change unless the baseline AMP is also adjusted.

One manufacturer group recommended that manufacturers be allowed, but not required, to adjust baseline AMPs. The group was concerned that a requirement to adjust baseline AMPs would be impractical for some manufacturers due to data availability and operational burden issues.

Another manufacturer group recommended that CMS work with manufacturers to develop reasonable methodologies to adjust baseline AMPs.

As a related issue, two manufacturer groups commented that any changes in AMP methodology should be made only prospectively and not retrospectively.

RECOMMENDATIONS

We recommend that the Secretary direct CMS, in promulgating the AMP regulation, to:

- clarify requirements in regard to the definition of retail class of trade and the treatment of PBM rebates and Medicaid sales and
- consider addressing issues raised by industry groups, such as:
 - administrative and service fees,
 - lagged price concessions and returned goods,
 - the frequency of AMP reporting,
 - AMP restatements, and
 - baseline AMP.

We also recommend that the Secretary direct CMS to:

- issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and
- encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In commenting on a draft of this report, CMS stated that it would address each of the recommended areas, as well as the areas raised by industry groups, in its proposed regulation. CMS also stated that it would evaluate the need for additional guidance.

CMS's comments are included as Appendix G. Attached to those comments were technical comments, which we addressed as appropriate.

APPENDIXES



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

March 31, 2006

Marcia Sayer
External Affairs
Office of the Inspector General
330 Independence Ave, SW
5th Floor, Room 5541
Washington, DC 20201

The Biotechnology Industry Organization (BIO) appreciates this opportunity to provide comments to the Department of Health and Human Services Office of Inspector General (OIG) regarding the content of its report to the Secretary and Congress, due June 1, 2006. That report is to contain recommendations regarding the calculation and reporting of Average Manufacturer Price (AMP) under section 1927 of the Social Security Act.

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

BIO accepted the OIG's invitation to meet on March 15, 2006 to describe our views about the requirements for, and the manner in which, average manufacturer prices are determined. At that meeting, the OIG representatives requested that BIO supplement its discussion in the meeting with a written submission, by March 31, 2006. This letter responds to that request. As we noted in that meeting, the central principle of BIO's comments is that the OIG's recommendations should promote consistency, clarity, and economic fairness in the calculation and reporting of AMP.

Monthly Reporting of AMP

The Deficit Reduction Act (DRA), at section 6001(b)(1), changes the current quarterly reporting timetable for Average Manufacturer Price (AMP) and Best Price (B) to a monthly period. This monthly reporting is meant to facilitate the use of AMP figures to set monthly Federal Upper Payment Limits, or FULs, under

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DRA section 6001(a) for multiple source drugs. While the DRA did change the AMP and BP reporting timetable, the DRA did not change the statutory definition of "rebate period," i.e. the period for each state rebate claim, contained at 42 U.S.C. § 1396r-8(k)(8), which remains "a calendar quarter or other period specified by the Secretary." Given the intended use of AMPs to set reimbursement rates and the current inconsistency between the statutory reporting and rebate periods, BIO requests that the OIG's recommendations address the following issues:

1. Monthly calculation of AMP figures. The OIG recommendations should specify whether or not the new monthly timetable for reporting AMP figures also requires manufacturers to calculate AMP figures on a monthly basis, as opposed to requiring manufacturers to report a quarterly AMP figure on a monthly basis. This clarification is of paramount importance and necessary so that manufacturers can prepare for the 2007 implementation timetable.

2. The calculation methodology for monthly AMP figures. If the OIG recommends that the DRA be interpreted to require monthly calculation and reporting of AMP figures, then the OIG recommendations should also address the methodology for calculating AMP on a monthly basis. The use of monthly AMP figures to set reimbursement rates suggests that such figures, like Average Sales Price, should be final when submitted and not subject to manufacturer revisions during the three year restatement period currently permitted by regulation (42 C.F.R. § 447.534(h)(2)(i)). The OIG recommendations should address this issue. In doing so, the OIG recommendation should consider the significant added administrative burden and operational complexity that a requirement to restate monthly AMP figures would impose on manufacturers, CMS, and the States.

If the OIG recommendation is that monthly AMP figures should not be subject to subsequent revision by manufacturers, then the OIG recommendations should also address in specificity the methodology that manufacturers should use to estimate late-arriving data that is used to quantify AMP-eligible discounts and rebates and AMP-ineligible sales, the level of accuracy needed for such calculations, as well as the process for manufacturers to follow should they discover errors in previously submitted figures.¹ Whether the OIG recommends for or against the continued availability of the restatement period, given the prevalence in the industry of quarterly performance periods under discount and rebate contracts, the OIG recommendations also should address how such quarterly discount measurements should be accounted for in a monthly calculation.

¹ While the DRA does not direct the OIG to also provide recommendations regarding the calculation of Best Price, should the OIG recommend that AMP and BP figures not be subject to revision, BIO requests that the OIG also recommend a methodology for accounting for late-arriving data in the calculation of Best Price.

3. The statutory rebate period. The OIG recommendations should address whether the rebate period should continue to be a quarterly one, and if so, how the quarterly rebate amount will be derived from reported monthly AMP and BP figures.² For a quarterly rebate period, a possible solution is to require manufacturers to submit a quarterly weighted average AMP figure with its monthly submission for the third month of the quarter, with the quarterly weighted average AMP being derived from the AMPs reported for each of the months in the quarter and weighted based on AMP-eligible units for each month. Another approach would be to have manufacturers calculate monthly AMPs for the first two months of the quarter, but have the AMP for the third month of a quarter be calculated as a quarterly figure. Either approach would also provide a solution for calculating future base date AMP figures, which the Medicaid statute requires be determined based on the statute's quarterly rebate period, see 42 U.S.C. § 1396r-8(c)(2)(A), as well as for deriving Public Health Service Ceiling Prices, which federal law also requires to be derived from quarterly prices, see 42 U.S.C. § 256b(a)(2).

The OIG recommendations should also address whether manufacturers would be permitted to revise such quarterly AMP figures to reflect late-arriving data relating to AMP-eligible discounts and rebates and AMP-ineligible sales. Even if the OIG were to recommend against the availability of such revisions in relation to the AMP figures reported on a monthly basis and used to set reimbursement rates, the OIG recommendations should separately address the availability of such revisions for the AMP figures used to calculate Medicaid unit rebate amounts, and if the ability to make such revisions remains available, whether such revisions are mandatory. The continued availability of the 3-year restatement period would permit manufacturers to ensure that the AMP figures used to calculate rebate amounts are as accurate as possible and based on actual sales and discount data. However, given the added administrative burden of such revisions to both manufacturers and the States, should the OIG recommend against the availability of restatements for monthly AMP figures and direct the use of estimation methodologies for that reason, the OIG should permit manufacturers also to choose to rely on those monthly AMP figures for purposes of deriving an AMP for the rebate calculation. Manufacturers should be permitted to revise those AMP figures, to reflect late-arriving actual sales data, but not be required to do so.

4. Effective date for monthly reporting. The DRA, at section 6001(b)(1), requires CMS to begin its own monthly reporting of AMP figures to the States on July 1, 2006, using "the most recently reported average manufacturer prices." The DRA change to a monthly reporting timetable for manufacturers does not include its own effective date, and therefore appears to be governed by section 6001(g) of the DRA, which provides for an effective date of January 1, 2007

² BIO notes that any recommendation to change to a rebate period that is shorter than a quarter would require a significant implementation preparation period for manufacturers as well as the States.

where effective dates are not otherwise provided. Given the significance of this effective date to manufacturers, the OIG recommendations should confirm that that the monthly reporting obligation for manufacturers begins with the AMP and BP figures for January 2007.

5. Use of AMPs for Reimbursement Rates Prior to Issuance of Methodology Guidance. The DRA, at section 6001(a)(2), requires the use of AMP to set federal upper payment limits for multiple source drugs effective January 1, 2007, but, at section 6001(c)(3), does not require CMS to issue its rule regarding the AMP calculation until July 1, 2007. BIO believes that any AMPs used to set reimbursement rates should be calculated using a standardized methodology that is the result of input from all government and private-sector stakeholders, to ensure that the resulting reimbursement rates are fair and equitable as well as to ensure that patient access is not adversely impacted by variation in manufacturer methodology assumptions. The OIG therefore should recommend that CMS either postpone the use of AMPs to set reimbursement rates until the effective date of its rule regarding the AMP methodology, or that CMS in the short term issue interim guidance that will apply to the AMP calculation until the rule is issued and effective.

Inflation Penalty Rebate Calculation and the Prompt Pay Discount

The DRA, at section 6001(c)(1), directs that customary prompt payment discounts extended to wholesalers no longer be included as a reduction to AMP starting January 2007.³ The inflation penalty component of the quarterly rebate calculation requires the comparison of an inflation-adjusted AMP for the first full quarter of sales (the base date AMP) with the current quarter's AMP. Where the current quarter AMP exceeds the inflation-adjusted base date AMP, the difference is added to the Medicaid rebate. If customary prompt payment discounts are excluded from AMP only for the current quarter's AMP, and not also for the base date AMP, this comparison will falsely conclude that an inflation penalty is due for that proportion of the increase in the current quarter's AMP caused by the exclusion of the prompt pay discount.

The OIG recommendations should include a proposed methodology for avoiding this result. One approach would be to permit, but not require, manufacturers to recalculate their base date AMP figures to exclude customary prompt payment discounts, and to use those recalculated base date AMP figures for rebate calculations effective in 2007. The OIG should not require such a recalculation because, for certain manufacturers, data availability and the operational burden of such recalculations may make such recalculations impractical. For example, this approach would require many manufacturers to access pricing data that is many years old, stored in legacy information technology systems, and possibly relating to quarters outside of the 10 year document retention period specified in

³ The OIG recommendations should also confirm whether the definition of "wholesaler" in the Medicaid Agreement is the definition that should be used when interpreting this provision.

42 C.F.R. § 447.534(h). This approach also would require manufacturers and CMS to store and track two different base date AMP figures: one for rebate calculations relating to quarters prior to 2007 and one for quarters in 2007 and later years. As the recalculation of base date AMP would serve only to lower rebate liability, should the OIG choose this approach, manufacturers should be permitted to choose whether or not to recalculate their base date AMP figures.⁴

An alternative, and more streamlined, solution would be to revise the calculation methodology for the inflation penalty component of the rebate calculation so as to mathematically offset the impact of excluding prompt pay discounts for AMPs reported for January 2007 and later. One method for doing so would be to direct that the inflation penalty calculation include a standardized, formula-based upward adjustment to the base date AMP. For example, if the OIG were to conclude that the customary prompt payment discount percentage was 2%, then the OIG could recommend that the inflation penalty rebate calculation be adjusted to divide each reported base date AMP by .98, before applying the CPI-U based inflation factor, so as to upwardly adjust that base date AMP so that it no longer reflects customary prompt payment discounts. In this example, if the base date AMP is \$98, where it would be \$100 without inclusion of the prompt pay discounts, dividing that \$98 base date AMP by .98 will result in a revised base date AMP of \$100. This formula-based approach would have the advantage of avoiding the calculation and maintenance by CMS and manufacturers of separate base date AMP figures for rebate periods before and after 2007. This approach would also ensure that all manufacturers address this issue in the same manner.

Classes of Trade

The definition of AMP remains “the average price paid to the manufacturer for the drug in the United States for drugs distributed to the retail pharmacy class of trade.” 42 U.S.C. § 1396r-8(k)(1)A(). Very little written guidance exists from CMS regarding the definition of the retail pharmacy class of trade. The OIG recommendations should define the retail pharmacy class of trade with specificity. This definition should address particular classes of entities, examples of which are discussed below, but also include the general rule that the OIG recommends be used when evaluating entities not otherwise addressed by OIG or CMS guidance. Such a general rule will provide manufacturers with a crucial baseline for use in evaluating new entity types, and will promote the important goals of consistency, clarity, and economic fairness.

⁴ If the OIG recommendation is to permit manufacturer recalculation of base date AMPs, the recommendation should also address whether the manufacturer must use the same AMP methodology the manufacturer had in place during the base date quarter. Many manufacturers have revised their AMP methodologies over time to address CMS guidance, and a legacy AMP methodology also may no longer be supported by a manufacturer's information technology. For these reasons, the OIG recommendation should permit manufacturers to use their current AMP methodology to recalculate the base date AMP.

1. Classes of trade for which guidance is needed. Current CMS guidance either does address, or does not address with sufficient specificity, the retail or non-retail status of: physicians, clinics, patients (including coupon arrangements for discounts or non-contingent free product), Part D utilization, Specialty Pharmacy, Competitive Acquisition Program or CAP sales, Pharmacy Benefit Manager mail order and retail pharmacy utilization, State Pharmacy Assistance Program (SPAP) and Medicaid program utilization, and health care plan utilization. The OIG recommendations should address each of these entity types, define each such class of trade in a manner specific enough to permit manufacturers to readily determine into which category any entity should be placed, and specify the OIG's rationale for the recommended retail or non-retail status of each class.

2. Calculation treatment of discounts and units. The OIG recommendations should specify for each class of trade the treatment of gross sales, discount dollars, net sales, if applicable, and the respective sales units associated with that class of trade. Specifically, the OIG recommendations for each class of trade should specify (1) whether gross sales, net sales, and/or discounts extended to that class of trade should be used to reduce the AMP numerator, and (2) whether the units associated with that class of trade, whether identified through sales or reimbursement transactions, should remain in the AMP denominator. This specificity is necessary to ensure clear guidance regarding treatment of a given class of trade in the AMP numerator (sales dollars) and denominator.

Additional AMP Methodology Issues

In addition to the issues identified above, BIO requests that the OIG recommendations also address the following issues:

1. Prospective application only. The OIG recommendations should specify that any clarifications and/or changes in CMS directions regarding the calculation of AMP are to be applied on a prospective basis only. The very nature of the OIG recommendations and CMS' implementation of them suggests that they are changes to existing practice, provided because of the absence of guidance in the past. These changes therefore should be prospective only. Moreover, given the complexity of the DRA changes to the AMP calculation and reporting timetable, and the operational complexity that implementing those changes presents to manufacturers, the OIG recommendations also should specify that CMS implement the DRA changes using a single, prospective implementation date that provides manufacturers with a minimum of six months lead time to make the necessary preparations.

The OIG recommendations should also include a recommendation that any and all CMS guidance in the future specify whether that guidance is to be applied prospectively and or retrospectively. Should the OIG recommend that

monthly AMP and BP figures not be open to revision by manufacturers during the three year regulatory period, and should CMS adopt that approach, it will be even more imperative that any future CMS guidance regarding calculation issues be prospective in application only.

2. Service and administrative fees. The OIG recommendations should address the treatment of service and administrative fees paid to entities included in the calculation of AMP. Such guidance does exist as to the calculation of ASP, in the form of two Q&As (numbered 3318 and 4136 at the FAQ link at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>). However, the existing guidance for AMP is limited to that contained in Release to Participating Manufacturers 14, and does not provide needed specificity regarding the circumstances under which such fees may and may not be included in the AMP calculation. If the OIG recommends use of the same criteria in the AMP calculation as CMS has directed be used in the calculation of ASP, the OIG recommendations should clarify whether the definition of “bona fide service” is satisfied in relation to traditional wholesaler functions such as pick, pack, and ship services.

3. Methodology change review and approval process. The OIG recommendations should also address a process and timeline for approval of manufacturer-proposed AMP methodology changes. The current CMS process is described by CMS itself as one through which manufacturers submit requests for approval, and as to which CMS provides no response or resolution. The OIG should recommend a process that details the information needed with a submission, the criteria for approval, and a deadline for CMS resolution.

In conclusion, BIO appreciates this opportunity to provide comments to the OIG regarding its recommendations to CMS as to the calculation and reporting of Average Manufacturer Price. We hope our suggestions will help the OIG to identify and provide substantive recommendations that will help manufacturers submit the data needed to calculate appropriate Medicaid reimbursement and rebate amounts for drugs and biologicals. Please contact me at 202-312-9273 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Jayson Slotnik
Director, Medicare Reimbursement and
Economic Policy
Biotechnology Industry Organization

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April 20, 2006

Office of the Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC

Re: HHS OIG study of Average Manufacturer Price

As discussed during our March 16 meeting, GPhA has concerns over the implementation of the Medicaid reform legislation. These concerns are in the areas of reimbursement methodology and program administration. We recognize that there is a need for the Medicaid Program to realize savings through the continued and expanded use of generic prescription medicines. To that end, we need to work together to ensure that all entities in the supply chain retain incentives for the continued manufacturing and dispensing of generic medicines.

Methodology for Calculating AMP:

In order to understand GPhA's concerns regarding the importance of a clearly defined methodology for calculating Average Manufacturer Price (AMP), it is important to understand the typical chain of distribution for the products of generic pharmaceutical manufacturers. Generic pharmaceutical manufacturers currently distribute their products directly to warehousing chain pharmacies, mail order pharmacies, various managed care entities, wholesalers and distributors (who themselves resell to non-warehousing chain pharmacies, independent pharmacies, hospitals, clinics, etc.). For reference, warehousing chain pharmacies include, but are not limited to, Brooks / Eckerd, CVS, Rite Aid, Walgreens, and Wal*Mart; mail order pharmacies include Caremark, Medco, and Express Scripts; and wholesalers include AmerisourceBergen, Cardinal, and McKesson. (Note: Some large chains like Walgreens and CVS also have mail order divisions.)

The legislation contemplates not only the publication of manufacturer AMP data, but also changes to the methodology for calculating. As we understand it, the AMP is intended to account for all recorded sales and discounts within the reported period; however, as you are undoubtedly aware, fluctuating order patterns and erratic timing of transactions result

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in unpredictable fluctuations in AMP from month to month, or quarter to quarter based on customer mix, discount payments, returns and other normal business transactions. Moreover, given the ambiguity in the current regulatory guidance for calculating AMP, different manufacturers may very well be employing different assumptions either on their own or in conjunction with regulatory counsel to calculate their respective AMPs, which results in a variability across AMPs that prevents a true apples-to-apples comparison of pricing data across manufacturers.

It is also important to note that a manufacturer's AMP is actually a weighted average price, heavily influenced by the purchasing power of large national chain drug stores, and mass merchants. The prices paid by these volume purchasers generally are not available to others in the pharmacy community, including the independent pharmacies that portions of the Medicaid population rely upon.^{1,2} In areas where this is true, this inequity in pricing creates the potential for access to be a significant issue in the implementation of the proposed Medicaid reform. Whether sales to such volume purchasers should be included in AMP is just one of the questions raised by this legislation.

Another question concerns the legislation's current approach of using the lowest AMP reported for multi-source products upon which to base reimbursement. This model does not provide a means to measure:

1. De minimis sales volume associated with a given manufacturer's AMP,
2. A manufacturer's decision to sell a product to a single entity, regardless of volume, at a discounted price which would not represent a widely available price,
3. Discounts available to large volume purchasers based on the purchase of bulk package sizes; thereby creating a potential for reimbursement to be based on pricing that is not widely available, and in fact a statistical outlier,
4. The widespread availability to all pharmacy purchasers of certain manufacturers products,
5. The continued availability of a product for which an AMP is generated, and
6. Substantial wholesaler/distributor markup fees that apply to a majority of 30,000+ independent retailers/small chains (this subset represents almost 60% of U.S. retail pharmacy) that primarily purchase through wholesalers.

Whatever the answers to these questions, we ask only that your recommendations include a clear and concise methodology for calculating AMP that leaves no room for doubt as to the methodology that should be employed by each manufacturer in calculating AMP.

Program Administration:

In addition to the issues identified around the AMP calculation methodology, there are numerous procedural issues raised and many questions still surrounding the

¹ 2005 NCPA- Pfizer Digest

² 2005 NACDS Chain Pharmacy Industry Profile

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administration of the program. As an initial matter, despite the inherent ambiguity in the current AMP calculation methodology, the legislation appears to require CMS to make public the most recent manufacturer AMP data on or about July 1, 2006. Not only does this raise the variability issues, set forth above, but publishing this data not just to the states, but to the public at large, raises serious concerns about the evisceration of the private sector reimbursement model by displaying data known to be flawed. It is one thing to demand transparency under the guise of government accountability and provide this information to the states; it is quite another to eliminate certain pro-competitive advantages that one manufacturer may have over another in the public sector by publishing a baseline price as to each product of every manufacturer. CMS has the responsibility to publish a price that accurately reflects the market, nothing more.

Moreover, as outlined above, fluctuations and timing within the generic market make AMP reporting erratic and unpredictable. This currently occurs with the existing quarterly reporting requirements, and would only be exacerbated with monthly reporting. Products with low unit volume will have a disproportionate influence on the lowest AMP than potential higher AMP products with higher unit volume. This again reflects concerns over a system not designed around a widely available price, as the current FUL. AMPs could result from pricing available only to a certain minority of providers, yet become the reimbursement standard for the total pharmacy community. "Smoothing" will also have a huge impact on AMPs due to the large dollar value of chargebacks processed for wholesaler sales for generic products. CMS has been silent on smoothing in the quarterly AMPs, although CMS does require smoothing for ASP pricing for Medicare Part B. Generic manufacturers should be encouraged to smooth data in the AMP calculation for reimbursement to accommodate transaction timing.

GPhA and its member companies appreciate the opportunity to share our concerns and thoughts with the OIG and stand ready to provide additional assistance and input as this process moves forward.

Sincerely,



Kathleen D. Jaeger
President and CEO

Attachment: Questions to Consider

Additional questions for consideration by OIG

Once more clarity exists around the AMP calculation methodology, we would like to reserve the opportunity to discuss issues identified, which may include, but are not limited to the following:

- 1) Will manufacturers be required to submit a monthly AMP for FUL and quarterly AMP for rebates?
- 2) Will the government provide class of trades for all reimbursable entities in the US, so that these codes are not subjectively assigned by manufacturers? This will ensure consistency across manufacturers when calculating AMPs.
- 3) Will AMP for FUL be calculated at the 9 or 11 digit NDC? The price would be more accurate if calculated at the 9-digit level.
- 4) Explain the exclusion of wholesaler cash discounts? Does this apply to all customers?
- 5) Explain the separate reporting requirement for cash discounts
- 6) How does a manufacturer report a negative AMP calculation for reimbursement?
Comment: For the quarterly AMP for Medicaid rebates, CMS requires that the last quarterly positive AMP be reported.
- 7) Please explain how AMP and BP are to be calculated for brands/authorized generics? Will the AG give data to the brand for the brand's submission? If so, at what level of detail? Or will CMS calculate based on the Brand and AG's submission?
- 8) Similar to current AMPs/BPs, will the supplied monthly/quarterly AMP information for each manufacturer be kept confidential, not subject to the FOIA? It could have a negative effect on manufacturers if individual AMPs were posted.
- 9) Would a manufacturer be permitted to resubmit a monthly AMP for a prior submission?
- 10) Will there be an incentive to purchase generics via dispensing fees? Will the fees be a flat dollar amount or based on a percentage of AMP?



RECOMMENDATIONS FOR REGULATIONS DEFINING AMP

EXCLUDE PROMPT PAY DISCOUNTS

RECOMMENDATION

The regulations should affirmatively state that customary prompt pay discounts are not to be deducted when AMP is calculated.

RATIONALE

The Deficit Reduction Act of 2005 (DRA) amended the statutory definition of Medicaid Average Manufacturer Price (AMP) in Social Security Act § 1927(k)(1) by deleting the requirement for “deducting customary prompt pay discounts” when AMP is calculated. HDMA understands Congress took this action because prompt pay discounts are a common practice widely accepted across many industries and should be viewed as a financial transaction representing the time value of money and risk mitigation, not as a component of the cost of the product.

Regulations affirmatively addressing the proper handling of prompt pay discounts are needed to ensure that manufacturers are alert to the statutory change in the definition of AMP that Congress chose to make by deletion. Such an alert is particularly important since the requirement to deduct prompt pay discounts from AMP has been in place since the Medicaid drug rebate program began in 1991.

The DRA includes a safeguard provision designed to ensure that the elimination of the deduction of customary prompt pay discounts from AMP is not abused in that it requires manufacturers to report on “customary prompt pay discounts extended to wholesalers” when they report AMP. This safeguard, coupled with the industry’s longstanding use of prompt pay discounts, removes the need for implementing regulations that further define customary prompt pay discounts.

EXCLUDE WHOLESALER SERVICE FEES**RECOMMENDATION**

The regulations should affirmatively state that fair-market-value (FMV) fees paid to pharmaceutical distributors for distribution services that are actually provided by the distributor are not to be deducted when AMP is calculated so long as there is no implicit or explicit agreement between the manufacturer and the distributor requiring the fees to be passed on, in whole or in part, to the distributors' customers.

Service fees, derived from manufacturer – distributor negotiations, are structured in a variety of ways. The preamble to the AMP regulation should discuss factors that manufacturers and distributors should consider in determining FMV.

The preamble also should recognize that manufacturers may treat service fees as a reduction from total revenues for purposes of financial accounting even though the AMP rule instructs them not to deduct the fees when they calculate AMP.

RATIONALE

Both Finance Committee Chairman Grassley and Energy and Commerce Committee Chairman Barton stated in separate floor statements that, "It was not the intent of the conferees to suggest that by dropping bona fide service fees from the final agreement [Deficit Reduction Act of 2005] that those service fees should be included in the calculation of the Medicaid Average Manufacturer Price (AMP) reimbursement methodology as established in the pharmacy reimbursement provisions of the conference agreement."

CMS has provided guidance to the industry as a whole in the form of a Frequently Asked Question (FAQ) and directly to HDMA and Specialty Biotech and Distributors Association (SBDA) in a Dec. 9, 2004 letter, indicating that bona fide, FMV services fees should not be deducted when the Average Sales Price (ASP) is calculated. The stated rationale for the ASP instruct applies equally in the AMP context. Specifically, so long as service fees are not passed on to the distributors' customers, they "would not ultimately affect the price realized by the manufacturer."

In spite of the FAQ, manufacturers have not handled service fees consistently in their ASP calculations. Some manufacturers have elected to deduct service fees when ASP is calculated despite the FAQ instruction. These manufacturers have expressed concerns about how to determine whether fees are FMV. To avoid this same confusion in the AMP context, it is imperative for the AMP regulation itself or for the preamble to that rule to discuss how manufacturers can establish that service fees, including those set based on a percentage of associated drug costs and other services, are FMV.

Some manufactures have expressed concerns about the fraud and abuse risks associated with accounting for service fees differently for financial accounting and ASP purposes. They note that GAAP-accounting principals mandate treating fees as reductions to revenue when the fees are paid to a distributor that takes title to products and argue that failure to treat the fees as a price concession for ASP purposes creates an unacceptable disconnect between ASP reporting and financial reporting. They also note that accounting rules permit service fees to be treated as an expense on the income statement when a third-party logistics company is retained to distribute drugs without taking title to the products. As a result, these manufacturers argue that they must contract with such services rather than use traditional wholesalers to safely avoid having to deduct distribution costs from ASP, even if doing so is more costly or less efficient.

It is inappropriate and inequitable for the costs for very similar services, such as the distribution of drugs to providers, to be treated differently under a price reporting rule. There is already precedent for a similar disconnect between accounting and price reporting with respect to AMP. The IRS has ruled that Medicaid drug rebates should be treated as reductions to revenue even though the Rebate Agreement prohibits manufacturers from deducting the rebates when AMP is determined (Revenue Ruling 2005-28, published in Internal Revenue Bulletin 2005-19 (May 9, 2005)).

OIG and CMS should anticipate such accounting concerns in the AMP context and address them either in the regulation or the rule's preamble, by stating that bona fide, FMV service fees are not to be deducted when AMP is calculated regardless of whether those fees are paid to wholesalers or distributors that take title or to third-party logistics companies that do not, or incurred internally by a manufacturer that self-distributes.

MINIMIZE PERIOD-TO-PERIOD VARIABILITY IN AMP

RECOMMENDATION

The regulation should specify a smoothing methodology for accounting for all price concessions in the AMP calculation in a manner like that specified for use with lagged discounts under the ASP rule. The methodology should be well-defined enough to ensure consistent treatment by all manufacturers.

RATIONALE

The current instructions for calculating AMP are silent on whether chargebacks, rebates and other lagged discounts should be accounted for on an as-paid or an as-earned basis. As a result, different manufacturers have adopted different approaches. Some use the as-paid methodology for both chargebacks and rebates. Others use as-paid for chargebacks because the amount of chargebacks paid during a period is readily available within a few days after the period closes, but use an accrual approach for rebates. Still others accrue for both chargebacks and rebates.

Many large purchasers often buy pharmaceuticals in bulk and then sell from inventory for many months. The buying pattern can result in periods when a manufacturer's sales outstrip price concessions accounted for on an as-paid basis leading to an artificially high AMP, followed by one or more periods when discounts outstrip sales, leading to an artificially low AMP. Monthly reporting of AMP likely will exacerbate this problem. If a manufacturer elects to address this problem by accounting for lagged discounts on an accrual basis, it must periodically true-up AMP and Best Price reports to address accrual errors. Such true-ups can tax the capabilities of the rebate processing teams at the state Medicaid programs as well as the price reporting teams at the manufacturers. Moreover, the true-up approach, while it does allow for the eventual payment of the correct amount of Medicaid rebates, is inconsistent with the use of AMP prospectively as the reimbursement metric that will set the Federal Upper Limit (FUL) for multiple source drugs and, possibly, by some state Medicaid programs as a

reimbursement metric in formulas that determine the payment amounts that retail pharmacies will receive for drugs dispensed to Medicaid patients.

Because upfront discounts on large purchases meant to be sold out of inventory over an extended period of time can also distort pricing available to retail pharmacies in the market when they are factored into the AMP calculation on an as-paid basis, OIG/CMS should implement a well-defined smoothing methodology for handling all price concessions that must be considered in AMP that operates like the methodology specified for quantifying lagged discounts under the ASP rule. If OIG/CMS are not inclined to include upfront discounts in a smoothing methodology for AMP, it is imperative, particularly for multiple source products, that chargebacks be singled out for lagged treatment on a routine basis along with rebates despite the availability of as-paid chargeback data for a period within days after the period close because such chargebacks can often relate back to sales several periods prior.

EXCLUDE RETURN GOODS

RECOMMENDATION

The regulation should instruct manufacturers to disregard return goods when they calculate AMP.

RATIONALE

Returns to a manufacturer during a period of slow sales can actually result in a negative AMP. This, of course, is inconsistent with the use of AMP as a reimbursement metric, even for the limited purpose of setting FULs. There are two approaches to address this issue. First, as is the current CMS practice for rebate purposes, the government could revert to the last positive AMP for reimbursement purposes. Alternatively, returns could be disregarded in the calculation of AMP as they are in the ASP calculation. Given that comparisons between ASP and AMP are one of the pricing safeguards built into the ASP system, we favor the adoption of parallel rules for treating various parameters where appropriate. This would seem to be one of those situations.

PROVIDE FOR THE CALCULATION OF AMP AT 11-DIGIT LEVEL

RECOMMENDATION

The regulation should stipulate that manufacturers must calculate and report AMP at the 11-digit NDC level.

RATIONALE

Currently, in accordance with the terms of the Medicaid Rebate Agreement, manufacturers calculate and report AMP as a weighted average for a given drug, strength and dosage form across all package sizes. In other words AMP is tied to the first 9-digits of the National Drug Code (NDC) number and ignores the last two digits which represent package size.

The weighted average AMP reporting process can become problematic when the weighted average value is overshadowed by sales of one package that is significantly larger than other packages of the same drug name/strength/dosage form. The difficulty with applying the weighted average approach across all products is that physicians often dictate the package size a pharmacy must dispense. For example, a physician may prescribe a 15-gm tube of cream to treat a small rash. The price per gram for the larger 60-gm tube is typically less. Applying the 9-digit NDC price may cause an AMP-based reimbursement rate to be too low to fairly reimburse the pharmacy for the 15-gm tube.

Similarly, averaging the typically higher costs of products used extensively in long-term care (LTC) facilities (due to the added cost of packaging as unit doses) with the cost of the same product packaged for retail settings, artificially inflates the AMP of the product and simultaneously depresses the AMP for the LTC setting.

The definition of AMP in Social Security Act § 1927(k)(1), as amended by DRA, does *not* require AMP to be calculated as a weighted average across all package sizes. This approach was adopted by CMS when it

drafted the Rebate Agreement used in lieu of regulations to implement the Medicaid drug rebate program in 1991. Accordingly, CMS has the authority to change course and require 11-digit NDC-specific reporting of AMP, just like it has required 11-digit NDC-reporting of ASP. It is important to do so since States will be permitted to incorporate AMP into reimbursement formulas that will be applied to drugs dispensed to Medicaid patients by retail pharmacy.

EXCLUDE REBATES PAID TO PBMs ON RETAIL NETWORK SALES**RECOMMENDATION**

The regulation should stipulate that rebates that do not reduce the effective price, such as those paid to PBMs on retail network sales, are not to be taken into consideration when AMP is calculated regardless of whether those rebates are linked to sales to Part D PDPs or MA-PD plans.

RATIONALE

Brand manufacturers typically pay rebates to pharmacy benefit managers (PBMs) for prescriptions dispensed to enrollees at retail pharmacies that participate in the PBM's retail network. The rebate payments are made to PBMs, even though the PBM does not actually purchase or dispense drugs to which the rebates are attached. Those monies are not shared with the retailers and should not be treated as a price concession that reduces AMP now that AMP will be used to set FUL and may become an element in the formulas that some state Medicaid programs use to reimburse retail pharmacies.

CMS has never issued clear guidance on how manufacturers should treat rebates paid to PBMs for retail network sales for purposes of AMP and manufacturers have adopted differing approaches.

To encourage manufacturer discounting under Part D, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 excluded rebates paid to Part D PDPs and MA-PDs, or the PBMs that operate these plans, from the calculation of Best Price. The MMA did not, however, address how Part D rebates should be handled for purposes of AMP.

CMS has historically excluded price concessions carved out of the Best Price formula from consideration when AMP is calculated and it should take a consistent approach with respect to the Part D Best Price carve out. Doing so would be consistent with the need to carve PBM retail network rebates out of AMP when those rebates are on non-Part D sales.

March 16, 2005



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

APPENDIX D
Page 1 of 5

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GENERAL

March 21, 2006

The Honorable Daniel Levinson
Inspector General
U.S. Department of Health and Human Services
Wilbur J. Cohen Building
330 Independence Ave., S.W.
Washington, D.C. 20201

**Subject: Chain Pharmacy Recommendations Relating to Definition of Average
Manufacturers Price (AMP)**

Dear Inspector General Levinson:

The purpose of this letter is to supplement the comments that representatives of the National Association of Chain Drug Stores (NACDS) and the chain drug industry provided to staff of the HHS Office of the Inspector General (OIG) at our March 15, 2006 meeting regarding the calculation of the average manufacturers price (AMP). As you know, OIG is directed by the Deficit Reduction Act (DRA) of 2005 (P.L. 109-171) to make recommendations to the Centers for Medicare and Medicaid Services (CMS) by June 1, 2006 regarding the factors and methods that should be included in the calculation of the AMP.

NACDS represents more than 200 companies that operate more than 35,000 community retail pharmacies. Collectively, our membership base dispenses more than 70 percent of all retail prescriptions in the United States. Our membership will be significantly impacted by the use of AMP as a reimbursement benchmark because it could result in significant underpayments for prescription medications if not accurately redefined.

In general, "AMP is the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. AMP was created specifically in OBRA 90 to approximate the amounts that states were paying retail pharmacies for prescription drugs." In theory, the calculation of AMP is supposed to provide manufacturers with a credible value on which to base the rebates that they pay to states.

However, starting in January 2007, AMP will be used for the first time to set generic reimbursement rates for pharmacies. In addition, AMP values for single source and multiple source drugs will be made public and provided to the states starting this July. Therefore, accurate and consistent calculation of AMP is critical. AMPs must be calculated such that they are reflective of the prices at which retail community pharmacies purchase medications, or pharmacies will be underpaid for these medications.

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Although AMP has been calculated by manufacturers for over 15 years, clear direction and guidance has never been given to manufacturers by CMS. This has resulted in wide inconsistencies in these calculations. In addition, the definition of AMP has not kept pace with changes in the pharmaceutical marketplace since 1990. For example, when AMP was originally defined, there were few PBMs in the marketplace. However, rebates, discounts and price concessions given by manufacturers to PBMs and health plans have become an important component of today's pharmaceutical marketplace. In this letter, we reiterate the key points made at our meeting about the factors that we believe should be considered in the calculation of AMP.

- **Include Only Manufacturers' Sales to Wholesalers for Traditional Retail Pharmacies:** Only manufacturers' sales to wholesalers for products that are ultimately sold to traditional community retail pharmacies – traditional chain, independent, mass merchandise pharmacies, and supermarket pharmacies – should be included in the calculation of AMP. In our view, these are the only entities that should be considered the “retail class of trade.” Past audit reports done by the OIG appear to agree with that interpretation of “retail class of trade.” We also note that in CMS' final rule implementing the Medicare Part D prescription drug benefit program, the agency defines “retail pharmacy” as “any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.” Thus, it would be consistent with CMS' current Part D definition of “retail pharmacy” for the agency to indicate that only sales to true retail pharmacy establishments represent the “retail class of trade” for the purpose of calculating the AMP.

Given this suggested definition, only incentive-based discounts, rebates or other price concessions that are ultimately received by retail pharmacies should be deducted by the manufacturer from total retail pharmacy sales in calculating the AMP. Manufacturers should deduct chargebacks only to the extent that they know that these were provided for products sold by wholesalers to retail pharmacies. It is fair and reasonable that only amounts paid by manufacturers that are actually passed through to retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP.

- **Omit Mail Order and Nursing Home Sales in AMP Calculation:** Including manufacturers' sales of pharmaceuticals to wholesalers that are eventually sold to mail order pharmacies and nursing home pharmacies is inappropriate, in our view, even though CMS has instructed manufacturers to include sales to these purchasers. That is because these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts. These discounts are either retained by the PBM, or passed through in whole or part by the PBM to the payer. They are not made available to retail pharmacies. Thus, including these sales or rebates would lower the AMP for traditional retail pharmacies below their acquisition costs.
- **Omit Rebates paid by Manufacturers to PBMs:** When AMP was originally created in OBRA 90, PBMs had little prominence in the pharmaceutical marketplace. Now, most prescriptions are paid for through a third party entity – such as a PBM – that receives rebates and discounts from pharmaceutical companies.

Manufacturers should not deduct these amounts from their sales to retail pharmacies when calculating the AMP. That is because retail pharmacies do not receive these price concessions. Including PBMs' sales and discounts unfairly lowers the AMP, making it unreflective of sales to retail pharmacies. Medicaid also loses millions of dollars each year in manufacturer rebate revenues by including these non-retail sales in the definition of AMP.

- **Omit Customary Prompt Pay Cash Discounts Extended to Wholesalers:** As defined by law (and as amended by the Deficit Reduction Act of 2005), the AMP should be calculated without regard to prompt pay cash discounts extended by manufacturers to wholesalers. Cash discounts are provided to some retail pharmacies based on financing terms negotiated between the wholesaler and the pharmacy. These are not performance-based discounts. That is, a pharmacy may receive a small discount from the wholesalers or manufacturers for paying for the drugs in a shorter period of time than other purchasers. In addition, because not all pharmacies have the distribution infrastructure (i.e. warehousing and logistical capabilities) and cash flow to capitalize on these more favorable terms, the inclusion of prompt pay cash discounts in the calculation of AMP would be inappropriate. Given that the current rebate agreement defines wholesalers as "any entity (including a pharmacy or chain of pharmacies) to which the labeler sells covered outpatient drugs...", prompt pay discounts extended to chain warehouses that are also licensed as wholesalers should also be excluded from the AMP calculation.
- **Omit Payments made by Manufacturers for Bona Fide Service Fees:** Payments made by manufacturers to entities such as wholesalers and pharmacies for inventory management agreements or distribution service agreements should not be deducted from a manufacturer's retail pharmacy sales when calculating AMP. These payments reduce manufacturers' revenues from the sale of their drugs, but they do not lower the pharmacies' costs of purchasing prescription drugs. Moreover, not all pharmacies are able to participate in these agreements, so deducting them when calculating AMP would be unfair to many retail pharmacies. CMS has already determined that such fees should be omitted from the calculation of the "average sales price," the basis of payment for Medicare Part B drugs. Specifically, CMS has indicated that bona fide service fees are "expenses that are for an itemized service actually performed by an entity on behalf of the manufacturer, which would have been paid by the manufacturer at the same rate had these services been performed by other entities." OIG should recommend that a similar approach be adopted for AMP.
- **Omit Manufacturer Payments for Pharmaceutical Returns:** Each year, billions of dollars in expired and recalled pharmaceuticals must be returned by pharmacies and wholesalers to manufacturers. Manufacturers issue credit to wholesalers and pharmacies for these goods. Unfortunately, the level of credit provided is insufficient to cover the products' replacement value, the pharmacy's inventory cost of carrying the product to expiration, the reverse logistics cost of returning the expired and recalled product, as well as the administrative expense incurred by wholesalers and pharmacies to manage this process. A manufacturer's payment to a wholesaler or a pharmacy for expired and recalled merchandise as well as the fees for the associated services should be excluded from the manufacturer's AMP calculation.

If these payments and service fees are included in the AMP calculation, community pharmacies will actually incur not only the deficiency in the level of manufacturer's credit for the product and service, but also a reduction in reimbursement going forward for the associated products. Payments for expired and recalled pharmaceuticals and the associated services should not be interpreted as discounts or rebates and should be omitted from the AMP.

- **Omit Manufacturer Payments for Patient Care Programs:** Many pharmacies receive payments from manufacturers for performing certain patient care services, such as patient education and compliance and persistency programs. These payments should be omitted from the AMP calculation. These services provide valuable benefits to patients and overall the health care system because they improve patients' understanding of their medications and enhance patient compliance. Although they reduce the revenue that manufacturers receive on the sales of these drugs, they do not reduce the retail pharmacy's cost of purchasing the drugs. If these payments are included in AMP, pharmacies would lose incentive to offer these programs because it would reduce the value of the AMP, thus potentially reducing reimbursement. This could make it appear that the pharmacy's acquisition cost for the drug is lower than it actually is. Moreover, not all pharmacies participate in these programs so it would be unfair to many pharmacies to include these payments in the AMP.

Because of the wide inconsistencies in the way that manufacturers currently calculate AMP, we urge OIG to recommend that CMS not make the AMP data public this July until the agency publishes a final rule that defines AMP. We believe that a great disservice will be done to states, payers, consumers, and especially pharmacies by releasing data that have wide variability in their meaning, and are likely unreflective of the approximate prices paid by retail pharmacies for prescription medications. Only when the marketplace completely understands the methodology that is used to calculate AMP, as well as its relationship to the prices paid for pharmaceuticals by retail pharmacies, should the data be made public.

We also urge OIG to make several recommendations to CMS on how the agency applies the new Federal Upper Limit (FUL) for generic drugs which, beginning in January 2007, will be based on 250% of the lowest published AMP for a generic. In order to encourage continued generic drug dispensing in Medicaid, it is critical that the FUL be based on prices for products that are currently widely available in the marketplace. For example, we believe that only a generic product that is AB-rated in the FDA Orange Book, and is widely and nationally available to pharmacies for purchase in consistent supplies, should be used as the reference product to set the FUL.

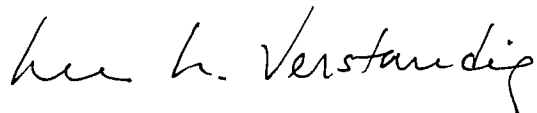
In addition, the AMP used as the reference product to set the FUL should be weighted by sales across all the package sizes of the particular dosage form and strength of the drug. The sales included in this weighted calculation should be those to retail pharmacies only. This will assure that the AMP is weighted according to the package size most frequently purchased by pharmacies. As we discussed at our meeting, we also believe that OIG should recommend that CMS adopt a process that would allow manufacturers, when calculating AMP for a quarter, to "smooth" over a rolling 12-month period of time any discounts or rebates that are passed through to retail pharmacies. This will help reduce the potential for any significant fluctuations in AMP from quarter to quarter, and maintain some consistency in reimbursement levels. Such a process was developed by CMS for manufacturers' calculation of the Average Selling Price (ASP), which is used as the basis for Medicare Part B drug reimbursement.

Without this process, it is very possible that upper limits for generics could be based on AMPs that are simply not reflective of the current market prices for drugs, further reducing generic dispensing incentives.

Finally, to assure that generic drug dispensing in Medicaid can be maintained or even increased, we urge that the FUL amount be the minimum payment that states make for a particular dosage form and strength of a generic drug. We believe that State Maximum Allowable Cost (MAC) programs for generics should be discouraged because further reductions in state payment for generics can ultimately result in reduced generic dispensing. States should also be advised of the need to consider increases in generic drug dispensing fees for 2007 to assure that pharmacies have appropriate incentives to continue to dispense lower-cost generic drugs.

We appreciate the opportunity to meet with you and provide our views on these important issues. Please contact us if we can provide any additional insight on these specific recommendations. We look forward to reviewing OIG's recommendation and to discussing these matters further. Thank you.

Sincerely,

A handwritten signature in cursive script, reading "Lee L. Verstandig".

Lee L. Verstandig
Senior Vice President, Governmental Affairs



To: OIG, HHS

From: Charlie Sewell, Vice President, Government Affairs

Date: March 16, 2006

Re: NCPA Comments on AMP provisions of Deficit Reduction Act of 2005

The National Community Pharmacists Association (NCPA) appreciates your continued interest in community pharmacy and for taking the time to meet today to discuss the issues, challenges and problems arising from implementation of the Deficit Reduction Act of 2005 ("the Act"). Most specifically, we are providing you with this comment memorandum regarding implementation of the Act and how its problematic use of a nebulously defined benchmark could have significant, harmful effects on Medicaid recipients, community pharmacies, local economies and states.

NCPA's Request:

In sum, NCPA requests that: 1) you use your authority to ensure that the definition of AMP covers all of pharmacists' acquisition costs; 2) the study of pharmacy reimbursement called for in the Act include an analysis of state-determined dispensing fees to ensure that pharmacy operating costs are adequately covered under state reimbursement formulas; and 3) HHS promulgate the rules on implementing that Act no later than September 1, 2006 to provide adequate time for community pharmacies to prepare for the implementation of these major changes in the Medicaid program.¹

The Troubling Result From Using AMP:

NCPA represents the nation's community pharmacists, including the owners of more than 24,000 pharmacies that dispense nearly half of the nation's retail prescription medicines. Because many Medicaid recipients depend on their local community pharmacies to provide them with needed medication, NCPA is compelled to alert you to language in the Act that negatively affects the costs savings that could otherwise benefit drug purchasers, States and the federal government.

As you know, the Act greatly reduces pharmacy reimbursement on generic drugs for Medicaid prescription drug recipients. The law ties reimbursement to a price index known as the Average Manufacturers Price (AMP). Leading generic drug manufacturers estimate that, as currently defined by the Manufacturers Rebate Agreement, **AMP will, on average, only reflect 50% of actual ingredient**

¹ The new Medicaid law requires that CMS disclose, starting July of 2006, the AMP pricing data to state Medicaid programs and the public. Unfortunately, the Secretary is not required to implement a regulation defining AMP until July 2007, one year after the AMP data are made public.

cost for generic drugs. Considering the unknown reliability of AMP and insufficient dispensing fees, the planned Federal Upper Limit (FUL) as contained in **the Act will effectively gut the reimbursement for generic drugs** under the Medicaid program. In stark contrast, brand name drugs are unaffected, and will be the only drugs on which pharmacists will be able to recoup their costs.

The result of promoting the use of brand name drugs over generics would be very costly. For every one percent of market share filled with a brand name drug that could be filled with a generic, Medicaid – and thus needy beneficiaries and taxpayers – will lose hundreds of millions of dollars. The lowest generic fill rate among states failing to promote generic drugs is 42%. If AMP is not correctly defined, and if dispensing fees are not increased, the potential for savings from generic drug utilization will be lost. An inadequate reimbursement level and concomitant decrease in use of generics will drive many pharmacies from the Medicaid program. Access in rural areas of the country could be particularly harmed. This resulting lack of access to quality prescription care will drive state Medicaid expenses higher as more patients require emergency room or nursing home care.

This outline of resulting harm is realistic, yet difficult to quantify. Estimating the real financial impact on retail pharmacies is extremely difficult because CMS has not publicly released AMP or issued clear guidance on how manufacturers should calculate AMP.

Based on how AMP is currently reported by manufacturers, it is clear that harmful consequences would follow from using the current AMP. NCPA respectfully urges you to use the wide statutory authority granted HHS regarding the definition of AMP to ensure that it covers 100% of pharmacists' acquisition costs. Doing so would ensure adequate reimbursements for generic drugs, thus promoting savings to the government and the health care system.

Problems With Using AMP as the Bench Mark to Determine Reimbursement Amounts and Rates:

In theory, AMP data approximates the prices at which retail pharmacies purchase medications from manufacturers via wholesalers.² For various reasons that are discussed below, however, AMP data is not at all likely to reflect the prices at which retail pharmacies purchase drugs. Because AMP was created, and is used, as a benchmark for rebate payments paid by manufacturers to state Medicaid programs, there is an inherent incentive on the part of the manufacturer to report the lowest price possible – a price that does not reflect true market costs for community pharmacy.

This fundamental problem in creating, using and monitoring the use of AMP is manifest in the following structural flaws:

- Currently, each manufacturer defines AMP differently, thus creating great inconsistencies in what is reported to CMS. In a February 2005 study (GAO-05-102), the Government Accounting Office reported that these inconsistencies are documented in the four Office of Inspector General (OIG) reports on audits of manufacturer-reported prices since the programs inception in 1991 (the reports were issued in 1992, 1995, 1997 and 2001). The GAO reported that the OIG reviews found “considerable variation in the methods that manufacturers use to determine AMP and some methods could have reduced the rebates state Medicaid programs received.” (GAO-05-102

² AMP is defined by statute as the average price paid to a manufacturer for the drug by wholesalers for drugs distributed to the retail pharmacy class of trade. *See* 42 U.S.C. §1396r-8(k)(1). There is no definition in the statute for “retail pharmacy class of trade.”

at p.5). Furthermore, “in four reports issued from 1992 to 2001, OIG stated that its review efforts were hampered by unclear CMS guidance on how manufacturers were to determine AMP, by a lack of manufacturer documentation, or by both.” (*Id.*, p.4).

- The GAO study found that **clear guidelines on how AMP is to be calculated have not been issued by CMS, nor has CMS resolved price determination problems.** “OIG found problems with manufacturers’ price determination methods and reported prices. However, CMS has not followed up with manufacturers to make sure that the identified problems with prices and price determination methods have been resolved” (*Id.*).
- Examples of some manufacturers taking advantage of the opportunity to alter AMP include:
 - Sales to mail order pharmacies and nursing homes when calculating AMP. Because mail order and nursing homes pay lower prices than retail pharmacies, including them in the calculation lowers the AMP below the price a traditional retail pharmacy pays.
 - Rebates paid to health plans and Pharmacy Benefit Managers (PBMs) when calculating AMP. These discounts are typically extended to bulk purchasers such as chain pharmacies, major wholesalers, and mail-order facilities that buy directly from the manufacturer. These discounts are simply not available to independent pharmacies, further widening the gap between AMP and market price.
 - These price concessions, however, are not available to retail pharmacies and therefore do not lower the pharmacies’ costs of purchasing prescription drugs. Including PBMs’ sales and discounts may lower the AMP to a level that does not reflect the cost to a retail pharmacy.
 - As the manufacturer must pay rebates based on AMP, the manufacturer then has an incentive to report the lowest numbers possible.
- Wholesaler costs and margins will not be covered by AMP. Federal law also makes few provisions for state determined dispensing fees which will become critical in ensuring that the professional services of pharmacists remain available to Medicaid patients.
- State MAC lists currently are lower than the FUL – significantly lower for some products and in some states. If states follow their current practice, often states will reimburse below the 250%. A study is needed to evaluate what currently happens and to find out how much below 250% of AMP states are reimbursing.

Conclusion:

Since all reimbursement cuts will come from generic prescription drugs, the AMP must be defined to cover acquisition costs or a perverse incentive will be created to dispense brands that could end up costing the program much more. To avoid the drastic consequences employing AMP in a situation for which it was not designed, NCPA respectfully requests that you recommend that: 1) HHS use its authority to ensure that the definition of AMP covers all of pharmacists' acquisition costs; 2) the study of pharmacy reimbursement called for in the Act include an analysis of state-determined dispensing fees to ensure that pharmacy operating costs are adequately covered under state reimbursement formulas; and 3) HHS promulgate the rules on implementing that Act no later than September 1, 2006 to provide adequate time for community pharmacies to prepare for the implementation of the major changes in the Medicaid program.



April 7, 2006

VIA HAND DELIVERY AND E-MAIL

Daniel R. Levinson, Inspector General
Office of Inspector General
Department of Health and Human Services
Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Average Manufacturer Price Recommendations

Dear Mr. Levinson:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide the following information on the determination of Average Manufacturer Price (AMP) in response to the Office of Inspector General's (OIG's) request for input on these issues. PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA has a long-standing interest in working with the government to develop clear and carefully-considered rules on the calculation of Medicaid rebates and the reimbursement of pharmaceutical products. Given this interest, and the Government Accountability Office's (GAO's) finding that clearer guidance is needed regarding AMP calculations,¹ we were pleased that Congress recently charged the OIG with reviewing "the requirements for, and manner in which" AMP is determined and submitting any recommendations it considers appropriate "for changes in such requirements or manner" to the Centers for Medicare and Medicaid Services (CMS) and Congress.² We believe this mandate provides an important vehicle for helping to improve the clarity and

¹ GAO, Medicaid Drug Rebate Program, Inadequate Oversight Raises Concerns about Rebates Paid to States, GAO-05-102, 4 (Feb. 2005).

² Deficit Reduction Act of 2005, P.L. 109-171, § 6001(c)(3) (2006). Following its receipt of the OIG's recommendations, CMS must issue regulations clarifying AMP calculations, taking into consideration the OIG's recommendations, by July 1, 2007.

Pharmaceutical Research and Manufacturers of America

950 F Street, N.W., Washington, D.C. 20004 • Tel: 202-835-3500

consistency of AMP calculations, which will now, in addition to affecting Medicaid rebates, affect pharmacies' Medicaid reimbursement rates for certain pharmaceuticals.

We appreciate the recent opportunity OIG provided to PhRMA to meet and discuss these issues, and we have focused our written comments on several of the issues raised by OIG during that meeting. Specifically, our comments address the following topics: the function of AMP, defining the "retail pharmacy class of trade," the ability to capture transactions between downstream entities in manufacturers' AMP calculations, the timing and application of changes in AMP, the issues associated with using AMP as a reimbursement metric, and the frequency of AMP reporting. These comments are preceded by general principles that PhRMA hopes the OIG will consider as it develops recommendations concerning the methodologies and manner in which AMP is calculated.

- As a general matter, AMP calculations should result in a calculated price that represents the amount realized by the manufacturer for product sold and distributed to wholesalers in the relevant period for purchasers who are in the retail pharmacy class of trade.
- Guidance concerning the calculation of AMP should be formalized in regulations that give stakeholders adequate opportunity for notice and comment.
- CMS should apply its regulations prospectively and give manufacturers ample time to operationalize systems, policies, and procedures to support the new AMP calculation.
- CMS should issue regulations to ensure that AMPs that now will be used in reimbursement formulas are calculated in a way that avoids: (1) the need for retroactive restatements; (2) zero or negative amounts; and (3) unnecessary quarter-to-quarter volatility, which needlessly creates instability for providers who submit reimbursement claims.
- Any procedures developed by CMS should recognize that there may be instances that call for restatements of AMP notwithstanding efforts to ensure the accuracy of reported data.
- Because the DRA changes the definition of AMP, CMS should develop a mechanism to conform baseline AMPs to the revised statutory definition of AMP for purposes of the additional rebate.

* * *

A. Retail Pharmacy Class of Trade

AMP is defined by statute as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.”³ As Congress recognized in the Deficit Reduction Act of 2005 (the DRA) when it directed the OIG to develop recommendations, and CMS to issue regulations concerning AMP, there is a need for clear and consistent guidance concerning the definition and calculation of AMP. This need for clarity is particularly critical given the use of AMP to establish Medicaid drug rebates. Moreover, it will take on even greater significance because AMP also will be used to establish upper payment limits for State Medicaid prescription drug payments beginning in 2007. Notably, the statute does not define AMP as a metric that approximates pharmacy acquisition costs. As discussed above, AMP is defined as the “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.”⁴ The statute does not define AMP as retail pharmacy acquisition costs. Moreover, Congress further demonstrated its understanding that AMP does not directly measure pharmacies’ acquisition costs when it chose to apply a 2.50 multiplier to establish FULs for multiple source drug products.

CMS has issued guidance previously regarding the definition of AMP in the Medicaid Rebate Agreement, certain Medicaid Rebate Releases, and proposed rules, but it has not defined the term “retail pharmacy class of trade” or provided a comprehensive listing of which entities fall inside and outside the retail pharmacy class. The language in the Rebate Agreement bearing on this issue provides that:

[AMP] means . . . the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor’s national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP.⁵

In the preamble to proposed (but never finalized) regulations published in 1995, CMS similarly stated that:

[S]ales that a manufacturer makes to other than the retail class of trade must be excluded [from AMP]. Thus, sales where the buyer relabels or repackages the drug with another NDC number and sales through wholesalers where the manufacturer pays a chargeback for sales to an

³ 42 U.S.C. § 1396r-8(k)(1). Under the DRA section 6001, customary prompt pay discounts extended to wholesalers will be excluded from AMP calculations by 2007.

⁴ Id.

⁵ Medicaid Rebate Agreement, § I(a), *available at*, <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf>.

excluded buyer, such as a hospital, would not be considered sales to the retail class of trade.

We would also exclude from this definition direct sales to hospitals, health maintenance organizations and to distributors where the drug is relabeled under that distributor's NDC number because these entities are not considered the retail pharmacy class of trade. We would also exclude Federal Supply Schedule (FSS) prices from the calculations of AMP since the statute does not include FSS and FSS does not represent a retail level of trade.⁶

Finally, in Medicaid Rebate Release 29 (1997), CMS listed certain categories of sales as either included in or excluded from AMP. Specifically, the release provided that: (1) AMP includes mail order and retail pharmacy sales, "nursing home primary/contract pharmacy sales," and "sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC"⁷; (2) AMP excludes direct sales to hospitals, HMO sales, Public Health Service (Section 340B) covered entity sales, "state-funded only-pharmacy assistance programs," "VA/DoD excluded sales," Federal Supply Schedule sales, and "sales to other manufacturers who repackage/relabel under the purchaser's NDC"; and (3) sales to wholesalers are included in AMP "except for sales to wholesalers which can be identified with adequate documentation as being subsequently sold to any of the excluded sales categories."⁸ Although Release 29 clarified some issues, it did not address a variety of entities and arrangements that could affect the calculation of AMP. Moreover, Release 29 is likely outdated given the continuously evolving nature and functions of various entities in the pharmaceutical distribution chain.

For example, CMS has not specified whether other specific categories of sales are included in or excluded from AMP. Some of the customers not addressed in Release 29 include, for example, physician groups, clinics other than Section 340B covered entities, and patients (i.e., there is no guidance on whether patient coupons or other patient discount programs affect AMP calculations).⁹ There has also been a lack of clear guidance regarding whether rebates to PBMs or payors (including Medicare Part D plans) should be excluded from AMP calculations, and (if so) whether manufacturers should simply exclude the rebates themselves from AMP calculations or should remove from the AMP numerator and denominator the underlying sales to wholesalers to which the rebates are attributed.

⁶ 60 Fed. Reg. 48442, 48462 (Sept. 19, 1995).

⁷ The Rebate Agreement defines a "wholesaler" as "any entity (including a pharmacy or chain of pharmacies) to which the [manufacturer] sells the Covered Outpatient Drug, but that does not repackage or relabel the Covered Outpatient Drug." Rebate Agreement, § 1(ee).

⁸ Rebate Release No. 11 (1994) also states that "sales of hemophilic drugs to home health care providers must be included in the calculation of AMP," indicating that home health care providers would be considered part of the retail pharmacy class of trade. (Emphasis omitted.)

⁹ CMS has issued guidance on this topic in the Best Price context.

As a result of the unaddressed questions regarding the “retail pharmacy class of trade,” the GAO found that manufacturers made different assumptions about which entities were considered within the class.¹⁰ Consequently, to reduce manufacturers’ uncertainties and increase the consistency of AMP calculations, it will be important for the OIG to make strong recommendations regarding the clarification of these definitional issues.

In an evolving marketplace, terms such as “wholesaler” and “retail” may be interpreted in different ways by different companies and entities. Entities are more appropriately categorized for purposes of defining AMP by the actual functions they perform rather than by the names by which they generally are known at any given time. Thus, PhRMA believes that an optimum approach is to use function-based analysis that recognizes that the function of an entity in the distribution chain may govern whether particular transactions should be included in the calculation of AMP. We suggest the following function-based definitions for the key AMP terms: “wholesaler” and “retail class of trade.”

- i. **Wholesaler** shall mean those entities that purchase covered outpatient prescription drugs as defined in Section 1927(k) directly from the manufacturer, or its authorized agent, and that take legal title to the prescription drug product.
- ii. **Retail Class of Trade** (a) shall mean, subject to subsection (b), those entities or such subdivisions, departments or lines of business that:
 1. dispense covered outpatient drugs to patients, who are members of the general public on a walk-in basis, pursuant to a prescription, including for example, retail, independent, and chain pharmacy;
 2. dispense covered outpatient drugs to patients through the mail (or other common carrier) pursuant to a prescription and the patient does not receive other specialized or home care services in addition to the dispensed drug;and (b) shall not include such entities or such subdivisions, departments or lines of business that:
 1. only dispense covered outpatient drugs to inpatients of the entity (e.g., inpatient hospitals);

¹⁰ GAO, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concern, at 16.

2. administer the drug "incident to" a physician or other licensed prescriber's services' (e.g., physician offices);
3. dispense only to a defined and exclusive group of patients who have access to dispensing services (e.g., closed pharmacy, staff model HMO, or correctional facility);
4. are federal, state, or local government purchasers and those purchasing under the federal supply schedule (e.g., VA);
5. are exempt from best price (e.g., 340B entity, SPAP, Part D Plans);
6. are other wholesalers or distributors that do not dispense to patients;
7. negotiate or arrange for pricing terms for third parties but that do not take possession of the drug product (e.g., GPO);
8. repackage or relabel under the entity's own NDC; or
9. are entities to which sales below 10% of AMP are considered to be nominal sales under Section 1927(c)(1)(D).

All parenthetical examples are for illustrative purposes and manufacturers may document that sales to such an entity should be included or excluded in the retail class of trade based on its function in a manner that differs from the illustrative example. Two areas where it would be helpful for the OIG to provide recommendations concern the application of these functional standards to long-term care facilities, PBMs, and other entities that reimburse for drugs but do not take title or possession of the drug product.

B. Taking Into Account Transactions Between Downstream Entities in AMP Calculations

In PhRMA's recent meeting with the OIG, the OIG expressed interest in obtaining additional information on the pharmaceutical distribution chain and the flow of payments within the pharmaceutical system. The OIG also indicated that it was interested in this information on the pharmaceutical supply chain and payment system partly in order to gain an understanding of whether manufacturer payments were passed through by their recipients to other parties. In addition, the OIG asked whether it would be feasible for manufacturers to require contractually that recipients of

payments inform the manufacturer about whether the payments had been passed through to others.

As noted at the meeting, PhRMA does not obtain information on member companies' pricing practices due to antitrust concerns, and information on pricing and payment arrangements between many of the participants in the pharmaceutical system is closely held and generally unavailable to manufacturers in any case. However, we have included in the appendix a brief general overview of the pharmaceutical distribution chain and payment system, based on information from publicly available reports.¹¹ In addition, we address the question raised in the meeting about the feasibility of requiring contractual reporting of downstream payments.

In past guidance, CMS has sometimes suggested that whether a certain manufacturer payment should be taken into account in the manufacturer's pricing calculations may depend on whether the payment is passed through by its recipient to another party.¹² In recent Average Sales Price (ASP) guidance on service fees paid to buyers, CMS stated that "[b]ona fide service fees that are paid by a manufacturer to an entity, that represent fair market value for a bona fide service, and that are not passed on in whole or in part to a client or customer of an entity" should be excluded from ASP because "these fees would not ultimately affect the price realized by the manufacturer."¹³ However, the ASP analysis may not adequately capture the fluid nature of certain transactions with and among downstream entities or the role of different entities in the distribution chain. Accordingly, PhRMA believes that OIG and CMS should clarify that there is no automatic requirement that manufacturers affirmatively obtain information concerning transactions between downstream entities.¹⁴ We believe that such a requirement would create serious problems and urge the OIG not to recommend this approach. Manufacturers have no authority to demand that payment recipients disclose to the manufacturer whether they have shared the payment in question with their own customers or clients, and there is no guarantee that payment recipients would agree voluntarily to such disclosures. The payment recipient might reject such disclosure provisions due to, for example, concerns about its ability to

¹¹ Our discussion is based exclusively on publicly available sources cited in the appendix. Principal among the sources are (1) Federal Trade Commission, Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies, Aug. 2005 (FTC report); (2) Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain, report prepared for The Kaiser Family Foundation by The Health Strategies Consultancy LLC, March 2005 (Follow the Pill); (3) Navigating the Pharmacy Benefits Marketplace, report prepared for the California HealthCare Foundation by Mercer Human Resource Consulting, Jan. 2003 (Navigating the Pharmacy Benefits Marketplace); (4) Study of Pharmaceutical Benefit Management, report by PricewaterhouseCoopers LLP for the Health Care Financing Administration, June 2001 (PricewaterhouseCoopers report); and (5) Department of Health and Human Services, Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices, April 2000 (HHS report).

¹² CMS alluded to pass-through issues in its rebate guidance on PBMs (which has caused interpretive difficulties), stating in part that "where the effect on the manufacturer for using the PBM is to adjust actual drug prices at the wholesale or retail level of trade, such adjustments need to be recognized in best price calculations." Medicaid Rebate Release No. 29 (1997).

¹³ CMS Frequently Asked Question ID 4136 (last updated Feb. 14, 2006).

¹⁴ At the same time, OIG and CMS should recognize the need for clear guidance concerning these transactions and their role (if any) in AMP calculations.

preserve the confidentiality of this competitively sensitive information once it was routinely disclosed to manufacturers; concerns about the administrative burdens associated with such reporting obligations; or concerns about the potential liability risks associated with furnishing manufacturers with information that would be used in the manufacturer's AMP calculations, and that could thus result in incorrect rebate payments and Medicaid reimbursement rates if the information turned out to be inaccurate in some respect. Consequently, manufacturers simply might be unsuccessful in negotiating contractual provisions requiring disclosure of pass-through information, or they could experience prolonged delays in negotiating contracts important to their ability to sell products or to acquire needed services.

Moreover, even if manufacturers could negotiate and enforce pass-through reporting provisions, the resulting information could be difficult to incorporate into a manufacturer's systems for calculating and reporting AMP. As discussed in the appendix, for example, PBMs' contracts with their clients do not have uniform provisions on the sharing of manufacturer rebates. To report whether the rebates paid by a manufacturer for a specific quarter were passed through, the PBM might need to determine the clients to which those rebates were attributable and separately identify pass-through and non-pass-through rebates. In turn, the manufacturer could not rely on a standard protocol specifying that (say) PBM rebates are taken into account in AMP calculations; instead, each AMP-reporting period, manufacturer personnel would need to review each PBMs' disclosure report and make case-by-case decisions about the appropriate treatment of PBM rebates in the AMP calculation. These kinds of frequent manual interventions in the AMP-calculation process could substantially increase the complexity of these calculations and heighten the risk of error, thus making it difficult for manufacturers to provide CMS with accurate AMP data on a timely basis. Similarly, delayed pass-through reports from payment recipients could complicate AMP calculations and cause overly burdensome restatements in previously reported AMP figures.

Given the problems with requiring that manufacturers contract with customers to obtain information on pass-through issues and then incorporate that information into their AMP calculations, we urge the OIG to recommend that CMS not adopt such an approach.

C. Other Issues

During PhRMA's meeting with the OIG on March 16th, PhRMA raised a number of issues concerning implementation of the AMP provisions in the DRA and changes to the definition and methodology used to calculate AMP. PhRMA's written comments and recommendations concerning several of these issues are set forth below.

1. Conforming Baseline AMPs to the New AMP Definition

The “additional rebate” for innovator drugs equals the current-period AMP minus the inflation-adjusted baseline AMP (usually the AMP from the first full quarter after launch).¹⁵ Because the DRA changes the definition of AMP, it raises the question of what mechanism should be used to conform baseline AMPs (as of the quarter when the AMP definition changes to exclude prompt pay discounts) to the revised statutory definition of AMP. The OIG may wish to recommend that CMS work with companies to develop reasonable methodologies to make this correction.¹⁶

2. Prospective Application of Clarification of AMP Guidance

The OIG should recommend that CMS issue regulations and guidance that make only prospective changes in AMP calculations. This recommendation would be consistent with the DRA, which calls for regulations that clarify “the requirements for, and manner in which, average manufacturer prices are determined,” not were determined in the past, and would recognize GAO’s finding that manufacturers have historically had to rely on reasonable assumptions in certain areas due to the absence of clear guidance.¹⁷ Prospective application of changes to AMP calculations would also avoid the difficulties and disruptions associated with industry-wide retrospective recalculations of past period AMPs.

3. Timing Issues Associated With Changes in AMP

The DRA contains a number of AMP-related provisions that take effect (or have deadlines) at different dates, which could result in a series of sequential changes to AMP calculations unless CMS makes an effort to synchronize the changes.¹⁸

Recognizing that manufacturers need sufficient lead time to change their systems and collect any additional data that may become relevant to AMP calculations, OIG should issue a recommendation that CMS provide adequate phase-in periods for any changes in AMP. The OIG also should recommend that CMS issue proposed and final AMP regulations as promptly as possible and seek to avoid a series of sequential changes in AMP calculations; frequent changes in AMPs due to a series of regulatory

¹⁵ See 42 U.S.C. § 1396r-8(c)(2).

¹⁶ We note that any changes in the existing requirements for calculating AMP that CMS adopts in its regulations on AMP calculations could raise similar questions regarding the baseline AMP.

¹⁷ DRA § 6001(c)(3). (Emphasis added.)

¹⁸ Some of the relevant dates for DRA AMP provisions are: June 1, 2006 (deadline for OIG recommendations regarding the requirements for and manner in which AMP is determined); July 1, 2006 (CMS must provide AMP data on a website accessible to the public); January 1, 2007 or earlier (AMP definition changes to exclude customary prompt pay discounts extended to wholesalers); January 1, 2007 (DRA section 6003 takes effect, which modifies the AMP definition “[i]n the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act”); and July 1, 2007 (deadline for CMS to issue regulations on AMP).

changes could heighten instability for providers that receive AMP-based payments for multiple source drugs, confuse the public (which will soon have access to AMP data), and require repeated changes in manufacturers' data collection and reporting systems. Similarly, the OIG may wish to caution manufacturers that changing their AMP reporting systems in response to the OIG recommendations could exacerbate these problems, as the final AMP regulations issued by CMS could differ from the OIG recommendations, and require that manufacturers adopt a different set of changes in AMP calculations.

4. Issues Associated With Using AMP as a Reimbursement Metric

Effective January 1, 2007, the DRA bases the Medicaid federal upper limit for multiple source drugs on AMP. Any recommendations or regulations should ensure that AMPs that are used in reimbursement formulas can be calculated in a way that avoids: (1) the need for retroactive restatements; (2) zero or negative amounts;¹⁹ and (3) unnecessary quarter-to-quarter volatility, which needlessly creates instability for providers who submit reimbursement claims. This could raise issues regarding AMP similar to issues that have been raised in the context of ASP (the drug reimbursement metric generally used under Medicare Part B).²⁰ Notwithstanding efforts to ensure the accuracy of reported data, there may be instances that call for restatements of AMP. This raises a dilemma given AMP's new role as a reimbursement metric, because the restatement could occur after a state has set the AMP-based reimbursement rates for a particular period. The OIG may want to formulate recommendations on a method for resolving this dilemma.

Moreover, the OIG also may wish to caution the states about the potential volatility associated with using AMPs that may change substantially due to sequential changes that will occur as the OIG issues recommendations in June 2006, and CMS issues a regulation by July 2007, concerning the new definition and clarification of AMP.²¹

5. AMP Reporting Frequency Issues

Section 6001 of the DRA appears to amend SSA § 1927(b)(3)(A)(i) to call for monthly reporting of AMP and Best Price.²² However, section 6003 then strikes section

¹⁹ Zero or negative amounts should not be an issue under existing CMS guidance, which provides that if a zero or negative AMP occurs in a given quarter, the manufacturer should report the last calculated AMP with a value greater than zero. Medicaid Rebate Release No. 38 (1998).

²⁰ As in the ASP context, returns should also be addressed.

²¹ The DRA requires the Secretary to make available to the states the AMPs for single source and multiple source drugs beginning in July 1, 2007. These AMPs may be substantially different from AMPs calculated after January 1, 2006 because of the newly promulgated definition of AMP which now directs manufacturers to exclude prompt pay discounts to wholesalers. Moreover, AMPs may change as a result of OIG's recommendations (due in June 2006) and CMS regulations (due July 1, 2007).

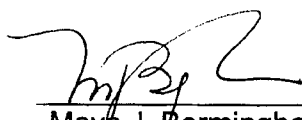
²² Section 6001(b)(1)(A) amends Social Security Act § 1927(b)(3)(A)(i) to state that manufacturers with rebate agreements shall report AMP and Best Price to the Secretary "not later than 30 days after the last day of each month of a rebate period under the agreement" (Emphasis added.)

1927(b)(3)(A)(i) and replaces it with new language that refers to AMP and Best Price being reported "not later than 30 days after the last day of each rebate period."²³ Thus, it appears that the law did not effectively change the frequency of manufacturers' reporting obligations. In the event that the DRA were to be interpreted to call for monthly reporting of AMP and Best Price, a number of issues would arise, and it may be helpful for OIG to develop recommendations on these points should they become relevant. OIG should recommend how quarterly rebates should be calculated and should recommend against basing rebates on weighted averages of monthly AMPs. In addition, OIG should recommend that restatements of quarterly AMPs continue to be permitted and that any monthly AMPs (should the statute ultimately be interpreted to require such calculations) not be restated.

* * *

PhRMA hopes that these comments will be helpful to the OIG as it formulates its recommendations to CMS and the Congress regarding AMP reporting and looks forward to providing additional input. We appreciate the time taken by OIG staff to meet with us and consider our comments, and the substantial effort your office is making to develop recommendations that can lead to clearer ground rules for AMP reporting and an improved system. Please do not hesitate to contact us with any questions or requests for additional information.

Sincerely,



Maya J. Bermingham
Assistant General Counsel



Ann Leopold Kaplan
Assistant General Counsel

²³ DRA § 6003(a)(1).

Appendix

Overview of the Pharmaceutical Payment System²⁴

While there is variation in the way that prescription drugs are distributed, the payment and pricing system is much more complex than the distribution system, and continually is evolving. Partly this increased complexity is because payment and pricing arrangements involve additional parties that generally do not play a role in the physical distribution of pharmaceuticals: in particular, PBMs and payors. As summarized in one report, “while the flow of products through the pharmaceutical chain is relatively straightforward, the flow of money involves a wider range of players and complex financial relationships.”²⁵ The discussion below begins with a general summary of the payment arrangements between the key entities involved in the distribution chain — manufacturers, wholesalers, and pharmacies —and then briefly describes some of the other participants in the payment system and the roles they play.

As noted earlier, manufacturers most commonly sell to wholesalers that resell to pharmacies. Manufacturers’ list prices to wholesalers are known as wholesale acquisition cost (WAC).²⁶ Wholesalers typically purchase at a discount off of WAC²⁷; examples of discounts for branded products include prompt pay discounts, volume discounts, and “short-dated” product discounts (where the wholesaler assumes the risk that the product will expire before it can be resold).²⁸ In recent years, the major wholesalers have sought to move to a “fee-for-service” model in which they negotiate fees with manufacturers for activities such as distribution and inventory management.²⁹

Pharmacies that purchase from wholesalers pay an amount negotiated with the wholesaler. According to one report, pharmacies typically pay wholesalers WAC plus some negotiated percentage.³⁰ In some cases, pharmacies or other “end-user” customers that purchase through wholesalers may negotiate rebate agreements with manufacturers, or they may negotiate a contracted price with the manufacturer. When

²⁴ As noted earlier, this appendix provides a brief general overview of the pharmaceutical distribution chain and payment system based on information in publicly available reports. Particularly given the complexity of the payment system, there may be arrangements or practices not captured in these reports.

²⁵ Navigating the Pharmacy Benefits Marketplace at 18.

²⁶ As defined in the Medicare Modernization Act, WAC represents “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . . as reported in wholesale price guides or other publications of drug and biological pricing data.” Social Security Act §1847A(c)(6)(B).

²⁷ Follow the Pill at 18.

²⁸ Id.

²⁹ See, e.g., R. David Yost, New Economics of the Pharmaceutical Supply Chain, 62 Am. J. Health-System Pharm. 525 (March 2005).

³⁰ Follow the Pill at 18.

wholesalers sell to customers that have a contract price with a manufacturer, they charge the contract price and then bill the manufacturer for a “chargeback”; the chargeback equals the differential between WAC and the contract price.³¹

Smaller pharmacies also may use group purchasing organizations (GPOs) in some cases to negotiate prices with wholesalers or manufacturers.³² GPOs are entities that negotiate discounted prices on behalf of their members (which primarily are hospitals and other healthcare providers) from manufacturers and distributors of pharmaceuticals and other healthcare products. Pharmaceutical manufacturers and other vendors pay administrative fees to GPOs, which (at least in the case of six GPOs that were studied by the OIG) distribute a portion of their administrative fee revenues to their members.³³

PBMs play a number of roles in the pharmaceutical payment system. Normally PBMs are not directly involved in the product supply chain, since they do not take physical possession or control of pharmaceuticals as part of their core pharmacy benefit management functions.³⁴ However, many PBMs own and operate mail order pharmacies and (in their capacity as mail order pharmacies) buy drugs from wholesalers or manufacturers and dispense them to patients.³⁵

PBM clients can generally be described as “payors.” That is, a PBM’s clients usually are entities that provide prescription drug insurance to their enrollees or members, such as self-insured employers, insurers, and HMOs and other managed care organizations.³⁶ The specific services a PBM performs will vary depending on its contract with particular clients, but PBM functions generally include forming pharmacy networks and negotiating discounted reimbursement rates with network pharmacies; developing and administering formularies and related features of the plan design (e.g., formulary tiering structures, utilization management tools such as prior authorization); negotiating rebates with manufacturers; and processing claims.³⁷

Payments that PBMs negotiate with manufacturers of brand-name drugs include rebates, and administrative fees that compensate the PBM for formulary-related administrative activities.³⁸ The effect of manufacturer rebates to PBMs on

³¹ Id. at 19.

³² Navigating the Pharmacy Benefits Marketplace at 25; Follow the Pill at 19-20.

³³ See HHS OIG, Review of Revenue From Vendors at Three Group Purchasing Organization and Their Members, A-05-3-00074, Jan. 2005 (the GPOs studied collected \$1.8 billion in administrative fee revenue during the audit period and distributed \$898 million to members); HHS OIG, Review of Revenue From Vendors at Three Additional Group Purchasing Organizations and Their Members, A-05-04-00073, May 2005 (GPOs studied collected \$513 million in administrative fee revenue during the audit period and distributed \$217 million to members).

³⁴ Follow the Pill at 14-15; FTC report at 7.

³⁵ Follow the Pill at 14-15; FTC report at 5-6.

³⁶ FTC report at v; PricewaterhouseCoopers report at 17. In some cases, these entities can be purchasers of drugs as well as payors; for example, some “staff model” HMOs operate on-site pharmacies at their facilities.

³⁷ See, e.g., PricewaterhouseCoopers report at 50-58.

³⁸ See, e.g., FTC report at 50-55. In some instances manufacturers also may pay PBMs fees for compliance, therapeutic interchange, and other programs related to particular drugs. Id. at 55. In addition to entering into

pharmaceutical prices has been described as follows: "This rebate does not affect the price paid by a wholesaler to a manufacturer for the drug, the price paid by a retail pharmacy to the wholesaler, or the price paid by the PBM to the pharmacy. It is a separate transaction between the PBM and the manufacturer and thus affects the total amount spent by the PBM. To the extent that a portion of the rebate is passed along, the insurer, employer, or beneficiary may realize a part of these savings."³⁹

Both the FTC's recent study on PBMs and an earlier study by PricewaterhouseCoopers reported that PBMs commonly pass through a share of manufacturer rebates, but not administrative fees, to their clients.⁴⁰ In addition, both studies indicated that the share of rebates passed through to a PBM's clients varies considerably from contract to contract.⁴¹ For example, the FTC examined the retention rates for all pharmaceutical manufacturer payments (including non-pass-through administrative fees) on 11 PBM contracts, and found that in 2003 the PBMs' retention rates on these contracts ranged from 25% to 91% (*i.e.*, pass-through rates ranged from 75% to 9%).⁴² The PricewaterhouseCoopers study reported that the percentage of rebates PBMs share with their clients can range from zero to 100%.⁴³

The FTC also noted that the percentage of manufacturer rebates that a PBM passes through to a client cannot be viewed in isolation, because clients make payments to PBMs (*e.g.*, administrative fees for claims processing and other services, and reimbursement for the drugs dispensed to plan beneficiaries) and a client could negotiate lower payments in exchange for receiving a lower percentage of manufacturer rebates. Thus, "PBMs could adjust any of a number of terms (*e.g.*, dispensing fees, discounts off of ingredient costs) to make the contract more attractive to plan sponsors" and "in this way manufacturer payments to PBMs could be passed on to plan sponsor clients through a complex array of adjustments to contract provisions relating, for example, to the services that would be provided by the PBM and the prices and fees that would be paid by plan sponsor clients."⁴⁴

agreements with PBMs providing for rebates and administrative fees, manufacturers may enter into similar agreements with insurers or other health plan sponsors that manage their own drug benefits, as well as with public programs that provide drug coverage.

³⁹ HHS report at 104.

⁴⁰ PricewaterhouseCoopers report at 9, 16, 52; FTC report at 59.

⁴¹ The FTC found that PBMs and their clients have agreements with three different types of rebate sharing models. In addition to contracting for a certain percentage of manufacturer rebates, PBM clients may also negotiate arrangements in which they receive a specific dollar amount per brand-name drug prescription from the PBM rather than receiving a share of the actual rebates paid to the PBM, or arrangements in which they receive a specified share of rebates subject to a guaranteed minimum rebate payment. FTC report at 57-58.

⁴² FTC report at 59.

⁴³ PricewaterhouseCoopers report at 88. See also HHS report at 105 (noting that industry sources report that PBM clients typically receive 70-90% of rebates).

⁴⁴ FTC report at 60. CMS made a similar point in a recent "call letter" to Medicare Part D plans; CMS stated there that "[w]e must assume that if a PBM retains a portion of the manufacturer rebates it negotiates on behalf of a Part D sponsor, the direct payment the sponsor pays the PBM for its services will be less, *i.e.*, the sponsor receives a price concession from the PBM." CMS PDP Call Letter April 3, 2006, at 10.

As noted earlier, PBMs also establish networks of retail and mail-order pharmacies where patients with PBM-administered benefits can fill prescriptions, and negotiate the reimbursement rates network pharmacies receive (*i.e.*, the total payment the pharmacy receives, including the PBM payment and the patient copayment or coinsurance amount). These negotiated reimbursement rates are lower than the rates that pharmacies charge to uninsured “cash-paying” patients, and usually vary depending on the restrictiveness of the pharmacy network (*i.e.*, pharmacies can obtain more business by participating in a more exclusive network, and may thus be willing to accept lower reimbursement rates).⁴⁵ The drug (“ingredient cost”) reimbursement rates negotiated between PBMs and network pharmacies reportedly are often based on a discount from Average Wholesale Price for brand-name drugs and a Maximum Allowable Cost limitation for generics;⁴⁶ pharmacies usually also receive a dispensing fee. The amount that the PBM itself is reimbursed by its clients may or may not equal the amount paid by the PBM to the pharmacy (*i.e.*, ingredient cost plus dispensing fee minus patient copay/coinsurance); the PBM may be paid for pharmacy costs based on a contractually-specified pharmacy reimbursement rate, and could thus experience a profit or loss on pharmacy costs.⁴⁷

The amount paid to the pharmacy by a patient depends on whether the patient is insured. Patients with insurance pay the copayment or coinsurance amount set by their insurer for the drug in question; uninsured patients usually would pay the “cash price.”⁴⁸ By one estimate, the cash price is approximately 15% higher than the pharmacy’s total payment (*i.e.*, insurance payment plus patient copay) for an insured patient.⁴⁹ Of course, insured patients ordinarily pay a premium for their coverage as well as the payments they make on prescriptions.

Although this brief overview of the pharmaceutical payment system cannot catalogue all of the system’s complexities, it suggests that the “price” of a pharmaceutical product is not easily captured and will depend on the perspective one wishes to examine. Rather than being a single number, the average “price” for a product at a particular time may vary depending on whether one examines the amount realized by the manufacturer; the amount paid by wholesalers; the amount paid by pharmacies; the amount paid by PBMs; the amount paid by PBM clients such as insurers or other health plan sponsors; or the amount paid by patients.

⁴⁵ FTC report at 5; PricewaterhouseCoopers report at 57, 70.

⁴⁶ PricewaterhouseCoopers report at 86-87; FTC report at 4-5; Follow the Pill at 19.

⁴⁷ PricewaterhouseCoopers report at 71; FTC report at 9-10.

⁴⁸ Patients with traditional indemnity insurance also may pay the cash price at the pharmacy counter and then submit a claim for reimbursement to their insurer.

⁴⁹ HHS report at 96.

APPENDIX G

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

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OFFICE OF INSPECTOR
GENERAL

TO: Daniel R. Levinson
Inspector General

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005" (A-06-06-00063)

Thank you for the opportunity to comment on the above draft report. This report looks at the manner in which the Medicaid average manufacturer price (AMP) is determined for drugs under the Deficit Reduction Act of 2005 (DRA).

As discussed in this report, the provisions of the DRA affected not only the Medicaid drug rebate program, but Medicaid reimbursement for drugs, as well. The DRA revises the definition of AMP to exclude customary prompt pay discounts to wholesalers. The DRA requires the OIG to review the requirements for and manner in which AMP is determined and recommend changes to the Secretary by June 1, 2006. The DRA also requires the Secretary to clarify the requirements for and the manner in which AMPs are to be determined by publishing a regulation no later than July 1, 2007.

Prior to the enactment of the DRA, AMP under the Medicaid program has been used solely to calculate drug manufacturer rebates. The DRA allows AMP to be used as a basis for reimbursement. States may use the publicly available AMP in setting their payment methodologies for retail pharmacies. The Centers for Medicare & Medicaid Services (CMS) will use the information to set Federal upper limits (FULs) on payments for multi-source drugs.

The OIG based its recommendations on information gathered through prior investigations. It also met with staff from CMS, Congressional staff, and stakeholder groups and analyzed written comments from six of the stakeholder groups.

OIG Findings and Recommendation

The OIG found that existing requirements for determining certain aspects of AMPs are not clear and comprehensive and that manufacturers' methods of calculating AMPs are inconsistent. While the OIG notes the history of CMS actions in clarifying the definition of AMP and recommends that CMS should consider further modification, it does not recommend a specific definition of AMP.

APPENDIX G

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Recommendations: The OIG recommends that CMS clarify requirements related to retail class of trade, the treatment of rebates to pharmacy benefit managers (PBMs), and the treatment of Medicaid sales. In addition, the OIG recommends that CMS consider addressing other issues that were raised by industry groups, specifically, administrative and service fees, lagged price concessions and returned goods, the frequency of AMP reporting, AMP restatements, and baseline AMP. Finally, the report recommends that CMS issue guidance in the near future addressing the implementation of the AMP-related reimbursement provisions of the DRA and encourage States to analyze the relationship between AMP and pharmacy acquisition cost when using this data source to determine payment rates to pharmacies.

CMS Response to Findings

The CMS acknowledges that the OIG has reported some confusion among drug manufacturers about what sales and price concessions must be included when calculating AMP. This is an extremely complex and technical topic that has been made more difficult due to changes in the chain of sales and the evolution of new entities, especially PBMs. For this reason, CMS had hoped that the OIG would have provided more specific recommendations for us to consider as we develop a proposed rule to address this topic. However, we appreciate the efforts of the OIG in the past, as well as this report, and we look forward to continuing to work with the OIG on this important issue.

CMS Response to Final Recommendation

In our proposed regulation to implement the AMP and reimbursement provisions of the DRA, CMS will take the opportunity to address each of the areas recommended by the OIG in this report as well as each of the areas raised by the stakeholders in the meetings with the OIG and subsequent written comments. We will issue the Notice of Proposed Rulemaking as expeditiously as possible. Likewise, we will review and respond quickly to public comments on the regulation, so that a final rule can be put in place as soon as possible. CMS will evaluate the need for additional guidance and provide this as we believe it would be beneficial.

Attachment